

Exhibit 5



London

This is to certify that the attached document is, to the best of my knowledge and belief a true, accurate and complete translation from Danish into English of the attached extract from U.2005.2151H regarding “No public liability under the Vaccination Compensation Act, as the suffering could not be considered caused by the MMR vaccination”.

Yours sincerely,

A handwritten signature in dark ink, appearing to read "Andrzej Orville", written over a horizontal line.

Andrzej Orville

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Wednesday, January 22, 2025

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U.2005.2151H

No public liability under the Vaccination Compensation Act, as the suffering could not be considered caused by the MMR vaccination.

Non-contractual compensation 111.2, 141.9, 21.2 and 21.9 - administrative law 24.9.

- ◆ On April 3, 1992, child B, who was almost 1½ years old at the time, was vaccinated against measles, mumps and rubella (MMR vaccination). 10 days after the vaccination, B developed a high fever that lasted for approx. 5 days. After the period of illness, B's motor skills became uncertain and her language development regressed. It turned out that B had developed infantile autism. B's parents, F and M, claimed compensation under the Vaccination Compensation Act, but both the National Board of Industrial Injuries and the National Social Appeals Board, A, which had previously obtained an opinion from the Board of Forensic Medicine, denied compensation. In this regard, A referred to the fact that the disorder - regardless of the temporal relationship between the vaccination and the onset of the disease - was not, with reasonable probability, caused by the vaccination. F and M brought the case before the High Court, during the hearing of which additional statements were obtained from the Board of Forensic Medicine. After an overall assessment of the medical information in the case, including various medical articles, the High Court did not find that there was a reasonable probability that B's autism was caused by the vaccination, and acquitted A. The Supreme Court upheld the judgment on those grounds.¹

H.D. April 19, 2005 in case 167/2003 (2nd district)

B via guardians F and M (counsel Bjarne E. Bødtker, Skjern, n.d.) against

The National Social Appeals Board (State Attorney via lawyer Henrik Nedergaard Thomsen, Copenhagen).

Western High Court***Judgment of the Western High Court March 12, 2003 (13th district)***

(Eva Staal, Ole Græsbøll Olesen, Helle Korsgaard Lund-Andersen (deputizing)).

In this action, brought on June 27, 1997, the applicant, B, represented by guardians F and M, claimed that the defendant, the Social Appeal Board, should be ordered to recognize that the applicant's condition (early infantile autistic syndrome) must be presumed to be a consequence of the vaccination which the applicant received on April 3, 1992 against measles, mumps and rubella (MMR vaccination) and thus covered by the Vaccination Compensation Act. The applicant claims, alternatively, that the case - for the

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event that the main claim be dismissed - be referred back for reconsideration by the National Board of Industrial Injuries/Social Appeals.

The defendant has requested acquittal.

The applicant was born on December 31, 1990 and has a twin sister, C.

The plaintiff has been granted legal aid and there is legal expenses for insurance coverage.

On December 18, 1996, the defendant made the following decision upon reopening the case, which had previously been decided by the National Board of Industrial Injuries on March 28, 1994 and by the defendant on October 19, 1994:

"...

The reported condition of infantile autism cannot be recognized as an MMR vaccination injury covered by the Act on Compensation for Vaccination Injuries.

The reasoning is that it cannot be considered proven that the disorder can be assumed, with reasonable probability, to have been caused by the MMR vaccination administered on April 3, 1992, cf. section 1(1) of the Act.

The National Social Appeals Board has emphasized that even though there is a temporal relationship between the vaccination and the onset of the disease, the examinations performed during hospitalization at Herning Central Hospital in the summer of 1992 have not established with reasonable probability that your daughter developed encephalitis in connection with the vaccination, just as there were no clinical signs of encephalitis during the febrile period that began 10 days after the vaccination.

The National Board of Appeal also emphasized the fact that permanent psychological damage, which may occur after encephalitis, only rarely occurs in the form of infantile autism, and that there is currently no medical evidence to suggest a link between MMR vaccination and autism.

As regards your question as to whether the infantile autism may not have arisen as a result of the vaccination without prior encephalitis, the National Social Appeals Board refers to the reply of February 6, 1996 from the Board of Forensic Medicine. As stated above, the National Social Appeals Board agrees with the opinion of the Medical Council.

As regards your lawyer referring to American studies published in 1973, the National Social Appeals Board notes that the results cannot be transferred to the Danish vaccination program launched in 1987. To the extent that vaccines that differ from the vaccines used in Denmark have been used in the referenced studies, there will also be no basis for using results from foreign studies.

The National Social Appeals Board thus upholds its decision of October 19, 1994, reported on November 1, 1994.

The basis for the decision:

...

Determining whether the necessary degree of probability, cf. the wording of section 1(1) of the Act on Compensation for Vaccination Injuries, is present depends on an assessment of the facts of the individual case in the light of the medical knowledge and experience available at any given time. A rule of evidence cannot therefore supplement or replace this medical knowledge and experience, which is the prerequisite for recognizing a disease as justifying compensation.

It appears from a report dated September 17, 1993 from the Children's Department at Herning Central Hospital that your daughter was vaccinated against measles, mumps and rubella on April 3, 1992. 10 days after the vaccination, your daughter developed a high fever of over 40 degrees. The attack lasted 5 days, after which the fever subsided. After this period of illness, your daughter's motor skills became unsteady, she seemed more hypotonic (slack muscles) and her language development slowed down, and she seemed withdrawn and difficult to make eye contact with. Your daughter's health conditions are described in a statement dated March 24, 1993 from the Children's Department at Herning Central Hospital, a statement dated December 16, 1993 from

¹ FT 1971/72, Forhandlingerne sp. 763, FT 1971/72, to B, sp. 2242, FT 1995/96, to A, p. 1377, FT 2002/03, to A, p. 6997, and Bo von Eyben: Patient insurance (1993), p. 83 et seqq.

Chief Physician Kai Erland Pedersen, Department of Child Psychiatry at Herning Central Hospital as well as a statement of February 11, 1994 from Adm. Chief Physician Ingelise Sillesen of the Children's Hospital in Risskov.

It appears that your daughter suffers from infantile autism. In addition, the National Board of Industrial Injuries obtained a statement in September 13, 1993 from Chief Physician F. Karup Pedersen, Rigshospitalet's Children's Department. In this statement it is stated that encephalitis (inflammation of the brain) after MMR vaccination has been described, but far less frequently than after natural infection with measles, mumps and rubella virus. Whether the febrile episode that occurred 10 days after MMR and Di-Te-Pol vaccination at 15 months of age was accompanied by encephalitis cannot be reliably assessed. The tests performed at the pediatric department of Herning Central Hospital were negative, but the tests were not performed until July, i.e. 3 months after vaccination. A negative result at this time does not rule out the possibility of previous encephalitis.

It has also been stated that patients with infantile autism often have minor signs of organic brain damage, e.g. in the form of EEG changes or findings in psychological tests that could indicate organic brain damage. It cannot be denied that encephalitis could be a contributing factor in the development of an autistic condition. The temporal correlation could be a link between the vaccination,

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subsequent cerebral effects and autism, but can of course not be considered as proof, just as no evidence of encephalitis has been found in the studies conducted, as described above. However, the negative studies cannot rule out that this may have been the case.

In the statement of December 16, 1993 from Chief Physician Kai Erland Pedersen, it is stated that it is not possible to have certain knowledge of a direct link between the specific vaccine that was used and your daughter's condition.

In a statement dated February 11, 1994 from Chief Physician Ingelise Sillesen, Children's Hospital, it is stated that as your daughter's clinical picture developed with high fever 10 days after vaccination, reduced general condition and then motor problems in the form of reduced tonus (muscle tension) and uncertain gait, language decline, lack of eye contact and changed behavior, it is difficult to imagine anything other than that there must have been a cerebral ("brain") effect, whether this was caused by the MMR vaccine or not.

It is further stated that there is no single etiological explanation for infantile autism, but it is now widely agreed that infantile autism is biologically determined and that the symptoms are caused by a cerebral dysfunction (brain dysfunction). A genetic predisposition (vulnerability) seems to play some role in some cases. Other causes include chromosomal and metabolic ("metabolic") disorders, cerebral infections and other central nervous system diseases.

After the National Social Appeals Board's decision on November 1, 1994, in a letter dated November 28, 1994, attorney Bjarne E. Bødtker, with regard to the requirement for proof of causality, cf. section 1(1) of the Act on compensation for vaccination injuries, generally referred to the wording "reasonable probability" in the Act.

The lawyer has pointed out that this wording indicates that the probability of causation requirement is at the low end of "the probability scale", and that the National Board of Industrial Injuries recently in a case of idiopathic thrombocytopenic purpura recognized the causal relationship "as a causal relationship could not be excluded". In the lawyer's opinion, the same argumentation and conclusion can be used in the present case, if the National Social Appeals Board does not immediately agree that the reasonable probability of a causal link can be excluded.

The correlation is fully documented, according to the already available specialist medical certificates from Chief Physician Kaj Erland Pedersen and Chief Physician Ingelise Sillesen.

The lawyer has also stated that similar cases of correlation between the MMR vaccine and subsequent brain damage (autism and the like) are still being investigated, both in Denmark and abroad, and that the National Social Appeals Board will be kept informed of these investigations.

The National Social Appeals Board subsequently obtained medical records from the medical center in Tarm and hospital records from Herning Central Hospital. This information shows, among other things, that B, since she was very young, has taken a long time to eat. In August 1991, when she was around 9 months old, she was referred to the pediatric ward of Herning Central Hospital due to eating problems during the transition to school meals.

During the Boel test at the age of 9 months, the nurse suspected hearing loss in B and her twin sister.

About 10 days after the vaccination on April 3, 1992, both twins developed a high fever. The doctor on call thought it was a throat infection and both twins were given penicillin treatment.

An MPU assessment was carried out at Herning Central Hospital in July 1992, where B was assessed to be at the 1-year level with regard to gross motor skills, fine motor skills, sense of touch and vision. It was assessed that B does not seem to react to verbal contact.

Stimulation with Wabletoner, Ewingsrangler and Boel test, performed in August 1992 at Herning Hospital, has shown normal hearing in the right ear, while there is a slower and uncertain response in the left ear.

B's disorder is described as classic, early infantile autistic syndrome in a statement dated November 16, 1992 from Chief Physician Kai Erland Pedersen.

During the reopening of the case, the National Social Appeals Board obtained an opinion from the Board of Forensic Medicine.

In response to the National Board of Appeal's question 1, "How is B's general condition and development prior to the MMR vaccination on April 3, 1992 assessed, including a request for the Board of Forensic Medicine's assessment of the significance of the fact that, around August 1, 1991 (at the age of 7 months), the child developed an eating disorder?" the Board of Forensic Medicine stated on February 6, 1996:

"Based on the available medical records from the pediatric department at Herning Hospital, the child had temporary eating problems in the summer of 1991. However, his well-being was not affected at any time. The problems subsided after counselling and, at the assessment on 9 Oct. 1991, the child was found to be in good order and was released. Based on this information and the information in the medical records of July 12, 1992, it must be assumed that the child had in all probability developed normally up to the time of vaccination on April 3, 1992. The temporary refusal to eat cannot, based on the available information, be attributed any significance in this context."

In response to the National Board of Appeal's question 2, whether it may have had an impact on the course of development that the child on March 24, 1992 had prolonged and febrile sinusitis purulenta, the Board of Forensic Medicine replied:

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"An extremely brief note on March 24, 1992, presumably from the patient's own doctor's (G. Hansen, Tarm) file, states that the patient at that time suffered from prolonged and febrile sinusitis purulenta. He was started on treatment with abboticin 140 mg x 3 daily. The medical record does not allow an assessment of the patient's condition at the time in question. Based on the available information, the Board of Forensic Medicine is therefore unable to comment on the possible significance of the sinusitis in question for the course of development."

In response to the National Social Appeals Board's question 3, "Can B

be assumed, with reasonable probability, to have developed encephalitis as a consequence of the MMR vaccination? During hospitalization at the Children's Department, Herning Central Hospital in July/August 1992, a 'spinal tap' (spinal examination) was performed on B. This was examined specifically for the presence of egg white elevation, as is generally seen in encephalitis. The Board of Forensic Medicine is asked to comment on whether the measured values indicate that B has had encephalitis," the Board of Forensic Medicine has stated:

"The examinations carried out at the pediatric department at Herning Hospital just over three months after the vaccination show normal cerebrospinal fluid without cells and with normal protein and no titers for morbilli, parotitis and rubella. CT scan of the cerebrum is, like the eye examination, normal. Hematological quantities, liver and fluid counts are all equally normal. Blood titers for morbilli and rubella are positive as regards IgG, but there are no detectable titers for parotitis. Metabolic screening for amino acids and volatile acids in the urine is negative, and lysosomal enzymes are also negative. MRI scan of the cerebrum on March 1, 1993 is also normal, apart from a slight asymmetry of the lateral ventricles which, in the opinion of the Board of Forensic Medicine, must be assessed as probably insignificant in this context. Finally, the hearing examination on March 23, 1993 is normal.

Thus, the tests performed cannot confirm that the patient had encephalitis following the vaccination. On the other hand, they do not rule out the possibility that the patient may have developed encephalitis, as in many cases such a condition does not give rise to lasting specific changes in the laboratory tests performed. For example, it is possible to have (have had) encephalitis without detectable changes in the protein in the spinal fluid. In such cases, the diagnosis must be made on the basis of purely clinical symptoms, with the uncertainty this entails. However, to the best of our knowledge, none of the symptoms usually seen in encephalitis, such as disturbances of consciousness, convulsions or paralysis, have been observed. The brief febrile state approx. 10 days after vaccination must be considered an expected vaccination reaction. Thus, it cannot be proven with reasonable probability that the patient has developed encephalitis as a result of the MMR vaccination.

In addition, it should be added that the Board of Forensic Medicine is not aware of any reliable information in the international literature for a correlation between MMR vaccination and autism. The fact that no event other than the MMR vaccination can be demonstrated which, based on a temporal relationship, could theoretically be thought to have a causal relationship with the patient's symptoms does not mean that this can be taken as evidence of such a connection, as it could only be a random coincidence.

Finally, it should be noted that encephalitis, for which there is no reasonable likelihood in this case, may cause permanent psychological damage, but only rarely in the form of the current condition, infantile autism".

To the National Board of Appeal's question 4, "If question 3 is answered in the affirmative: Can a mental disorder in B (the diagnosis of infantile autism has been made) be assumed, with reasonable probability, to be a consequence of the MMR vaccination?". The Board of Forensic Medicine answered: "Since question 3 cannot be answered in the affirmative, question 4 is cancelled".

In a letter dated February 20, 1996, lawyer Bjarne Bødtker asked whether infantile autism may have occurred after vaccination without prior encephalization, and whether the Board of Forensic Medicine does not find it thought-provoking that healthy children develop brain damage in connection with an MMR and Di-Te-Pol vaccination and, in this connection, consider whether a possible connection cannot be excluded. In a letter dated November 28, 1996, the lawyer also stated that it is his opinion that the burden of proof that the injuries found are not caused by the vaccinations should be on the public authorities when the cases

concerning B and another child have documented temporal coincidence, and especially because, in the opinion of the Board of Forensic Medicine, the children were healthy and well before the vaccinations.

You and the lawyer have the following preliminary comments on the Board of Forensic Medicine's statement of February 6, 1996: The Board of Forensic Medicine writes that none of the symptoms usually seen in encephalitis have been observed in B, such as disturbances of consciousness, convulsions or paralysis. Why does the Board of Forensic Medicine believe that the pediatricians at the children's ward at Herning Central Hospital subjected an 18-month-old girl to a spinal tap if it was not because of a suspicion of encephalitis? In your and your lawyer's opinion, the complaint is a long manifestation of the fact that your daughter was exposed to brain damage at the time in question. The lawyer quotes from the report: 15 month old vaccinated for MMR and De-Te-Pol together with her twin sister. 10 days after the vaccination there was a high fever, over 40 degrees. The girl was hospitalized for the next 5 days, and the

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fever spontaneously subsided, but the baby was never the same again. You couldn't make contact with her. Her development stalled and in some areas almost regressed. She went back to a blended diet, had to be fed, could no longer drink from a cup. She seems more hypotonic. It was difficult to get her to grab toys or roll over on her stomach, but you can still get her to crawl on the floor, sit nicely and play, and get up on furniture. Her gait is very unsteady and she seems very unstable in the hips. It is very difficult to make eye contact with her, she seems withdrawn and she is not interested in people, only in things. Her way of playing with toys is to sit on the floor and lick them.

The lawyer has also asked what the Medical Examiner's Council means when the child "seems more hypotonic, gait unsteady, unstable in the hips". Chewing and swallowing functions are also affected? If the fact that all contact with the child is suddenly impossible is not a disturbance of consciousness, then what is it?

MRI scans have shown that your daughter has a slight asymmetry of the lateral ventricles. In the lawyer's opinion, the fact that this is considered insignificant by the Danish Board of Forensic Medicine is incorrect, which is justified with reference to two articles. 1. JAMA 26 March 1973 and 2. Varied MR appearance of autism, by Martha Anne Nowell et al. From the article in JAMA you know that, especially in the winter months, there is a risk of encephalitis after vaccination for the measles virus, which leaves permanent neurological disturbances from mild attention disorders and motor agitation to deep mental retardation, and that encephalitis typically occurs about 6-11 days after vaccination. (In your daughter's case, the fever started on day 10). You know from the article in the American Psychiatric Journal that in 18 autistic patients there is slight asymmetry of the lateral ventricles. In this respect, autistic patients do not differ from patients with other neurological disorders. Your daughter's left frontal lobe brain cavity is slightly larger than the opposite one.

Therefore, in the lawyer's opinion, the Judicial Medical Council and the National Social Appeals Board should reassess the case based on the above comments and the enclosed articles.

Medical specialists have participated in the processing of the case at the National Social Appeals Board."

In connection with the presentation of the case in the defendant's decision, it appears from a medical record note dated June 23, 1992 from his own doctor, Dr. Georg Hansen, that the mother, M, found that B had suddenly stopped developing and that B "sits as if in a glass bell jar".

It appears from a letter dated January 4, 1993 from first registrar Malgorzata Pulczynska to Skejby Hospital, MRI center, that encephalopathy after vaccination was suspected.

The statement of December 16, 1993 from Chief Physician Kai Erland

Pedersen further states:

“...

Of significant recent material, we have read a report from 1989 from the German Monatschrift für Kinderheilkunde, an article that can be found in this journal, volume 137, issue 8 from page 440 to page 446, where the author's name is K.E.v. Mühlendahl.

The article describes 6 children over a 3-year period where there is a temporal relationship between measles/mumps vaccination and pediatric disease.

...

The article includes a literature review, which shows that, at the time, there were reports of 38 children with idiopathic thrombocytopenic purpura after the measles and mumps vaccination, while there were reports of 8 other children with meningism. It should be noted that the incidence of cerebral affection after vaccination is 13 times higher than the otherwise expected incidence (meningitis etc. that would have occurred after measles infection).

...

The direct link between the specific vaccine used for the child and early infantile autistic syndrome, which may well be a sequela of early encephalitis, cannot be known with certainty based on the available information.

However, one cannot help but be struck by the temporal progression (four of the meningitis cases mentioned occur between days 2 and 48 after vaccination, one on day 4, one on day 26, one on day 20 and one on day 5).

Furthermore, I should mention that we know from a not very old Swedish study that very few children with early infantile autistic syndrome do not show a brain organ substrate (Steffenburg in Developmental Medicine and Child Neuro-logy, 1991, volume 33, page 495).”

At the end of the statement of February 11, 1994 from Chief Physician and specialist in child psychiatry Ingelise Sillesen, it is stated:

“...

I do not think that there is anything to suggest that the girl's current autistic condition could have been caused by a possible encephalitis at the time. As the clinical picture has developed, I think there are grounds for suspecting that the girl may have had encephalitis, but whether the encephalitis was caused by the vaccination is, of course, something I cannot comment on other than that there is a certain probability of this due to the coincidence in time.” It appears from a report dated October 21, 1997 from Chief Physician Kai Erland Pedersen to the State's Serum Institute

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regarding febrilia after vaccination with subsequent developmental disorder, that the applicant's twin sister C had a fever of 40 degrees 11 days after the vaccination, that C has been diagnosed with Asperger's Syndrome and that it cannot be excluded that this has the same cause as the applicant's autistic syndrome.

On July 2, 1998, following the initiation of proceedings, the Council of Forensic Medical Examiners gave the following answers to three supplementary questions:

“...

Question 5.

The Board of Forensic Medicine's answer to question 3 states that “According to the information provided however, *none* of the symptoms usually associated with encephalitis have been observed, such as loss of consciousness, convulsions or paralysis.” In this connection, the Board of Forensic Medicine is asked to state whether this reply has taken into account, among other things, first assistant medical officer Malgorzata Pulczynska's notification letter of September 17, 1992 to the National Board of Industrial Injuries (sub-annex to annex 62 to the summons)

describing, inter alia, disturbances of consciousness, unsteady gait, instability in the hips and, if not, whether this information and/or the case file otherwise gives reason to change the answer to question 3.

1. Chief Physician Malgorzata Pulczynska's notification to the National Board of Industrial Injuries dated 17 Sept. 1992 has been included in the overall basis for the assessment of the patient and gives no reason to change the answer to the original question 3.

Question 6.

After reviewing appendices 63 and 64, articles in JAMA and Magnetic Resonance Imaging respectively, please explain why you find it insignificant that B (the plaintiff) has a slight asymmetry of the brain's lateral ventricles when the article in JAMA states that there is a risk of encephalitis after a measles vaccination, especially in the winter months, which leaves permanent neurological damage from mild attention disorders and motor agitation to deep mental retardation. The same article shows that the type of encephalitis in question typically occurs 6-11 days after vaccination.

The slight asymmetry of the brain's lateral ventricles has been assessed “as being probably insignificant in the context”, as the anomalies are quite slight and, it may be added, probably reflect a normal congenital variation, since no other signs of anatomical brain damage have been detected.

Question 7.

Please confirm or deny that the MMR vaccination *can* cause encephalitis and that encephalitis *can* cause early infantile autistic syndrome.

In rare cases, the MMR vaccination is thought to be a cause of encephalitis. However, there is no evidence that encephalitis causes early infantile autistic syndrome.

“...

On January 20, 1999, the Board of Forensic Medicine answered two further questions as follows:

“...

Question 8:

In connection with the Board of Forensic Medicine's answer to question 5, please specify why the Board of Forensic Medicine does not find that the described disturbances of consciousness, unsteady gait, instability in the hips, etc. can be certain clinical signs of encephalitis, as these clinical signs were the direct cause of various examinations of the claimant - including, among other things, a spinal tap. If the Board of Forensic Medicine maintains that these objective clinical observations, cf. first resident physician Malgorzata Pulczynska's letter of September 17, 1992, are “meaningless” in relation to the plaintiff's diagnosed autism, please inform the Board of Forensic Medicine how else these clinical observations should be interpreted.

In the letter of 17 Sept. 1992 from resident physician, Malgorsata Pulczynska, there is no mention of disturbances of consciousness. On the contrary it is stated that “her gait is very unsteady, and she seems very unstable in the hips”. This brief note is not accompanied by any actual description of abnormal objective findings, and the remark about unstable gait cannot be considered to be a specific symptom indicative of a specific disease. Nor does the note provide a basis for the Board of Forensic Medicine to elaborate on what the reason could be for the gait being described as unsteady with instability in the hips.

Question 9:

In connection with the Board of Forensic Medicine's answer to question 7, which states that there is no certain evidence that brain inflammation can lead to early infantile autistic syndrome, an article from Developmental Medicine and Child Neurology from 1991, pages 495-511, written by Susanne Steffenberg, is attached as appendix 71,

M.D. in child psychiatry, affiliated with Gothenburg University in Sweden. In the article, the author describes various causes of autism,

among other things.

Table 2 on page 501 mentions a child with autism-like disorders caused by encephalitis, and table 4 on page 502 mentions a child with autism who was found to have elevated protein levels in a spinal tap, which the author considers to indicate that the cause of the child's autism is a slow inflammation of the brain.

Attached as Appendix 71A is an article from Schizophrenia Bulletin vol. 7 no. 3 page 413 from 1981, which refers to another article in Archives of disease childhood vol. 50 pages 115-119, 1975, by Revenius, t.n. and others, where brain inflammation is also described as a direct cause of early infantile autistic syndrome.

The Board of Forensic Medicine is then asked to reassess the question of whether there is still relatively certain

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evidence that encephalitis *can* cause autism. References to the literature are all references to single case studies where coincidence between different events may be a coincidence or may have a possible causal relationship. However, these isolated cases do not allow for further analysis of probabilities or frequencies.

The literature cited thus does not give the Board of Forensic Medicine reason to change the answers to the previously asked questions.

“...”

Finally, on October 24, 2002, during a postponement of the sentencing hearing, the Judicial Medical Council answered questions 10 and A, B and C as follows:

“...”

Question 10:

After reviewing the case extract, the plaintiff's and defendant's material collection, the plaintiff's supporting documents in connection with the plaintiff's submission and documentation as well as the record sheet of September 29, 1993 prepared by Chief Physician Kai Erland Pedersen, Herning Central Hospital concerning B (civil reg. no. - - -), state whether the observations described in the record sheet of September 29, 1993 (Babinsky's toe phenomenon etc.) can, in the opinion of the Board of Forensic Medicine, be taken as evidence that B had encephalitis or another similar serious brain disorder earlier than the date of the examination.

After reviewing the case extract, the collection of material and appendices as well as the medical record description from Herning's Department of Child Psychiatry dated September 29, 1993 prepared by Chief Physician Kai Erland Pedersen, the Council has assessed the following:

- In July 1992 it is described that the EEG was normal
- It was reported in March 1993 that the MRI scan of the brain was normal. A slightly smaller size of the left occipital horn compared to the right cannot be considered abnormal or suggestive of cerebral injury.
- In his examination in September 1993, Chief Physician Kai Erland Pedersen found a slight predominance of tendon reflexes on the right lower limb compared to the left, whereas tendon reflexes were equal on the upper limbs. When stroking under the soles of the feet, a Babinski toe phenomenon was found, where the big toe moved upwards on the right side, whereas the big toe moved downwards on the left side. Babinski's toe phenomenon is usually present on both sides at birth and is gradually replaced during growth by a downward flexion of the big toe, as seen in older children and adults.
- There are no studies in the case file other than the one from September 1993 of the reflex conditions on the lower limbs to clarify whether this was an isolated finding or a finding that could be reproduced in repeated examinations.

Against this background, the Board of Forensic Medicine must conclude that the reflex disorders found in the right leg may be consistent with, but do not necessarily reflect, a prior previous brain

injury.

The EEG and MRI examination argue against, but do not necessarily exclude, a previous brain injury.

Question A:

Do the examination results in the medical record from Herning Central Hospital on September 29, 1993 indicate that the MMR vaccination caused the autism - or a disorder (brain disorder or similar) that subsequently caused the autism in B? The described reflex disorders cannot be taken as an indication that the previous MMR vaccination has caused the patient's autism or a possible related brain disorder.

Question B:

Do the examination results in the medical records from Herning Central Hospital on September 29, 1993 give the Board of Forensic Medicine cause to change any of the answers to questions 1-9 above?

The described findings do not give rise to any changes to the previously submitted answers to questions 1-9.

Question C:

Does the case give rise to any further comments from the Board of Forensic Medicine?

No.

“...”

In addition to the scientific articles mentioned in the defendant's decision and in the responses from the Board of Forensic Medicine, a number of other scientific articles etc. were referred to during the court hearing dealing with a possible connection between encephalitis and autism and between the MMR vaccination and autism. This includes an article from Schizophrenia Bulletin 1981 by Marian LK Demyer and others, which describes a study from 1979 in which encephalitis was described as the cause of autism in 149 cases of autism in children among a number of other causes. There is also an article from The New England Journal of Medicine from November 2002 by Kreesten Meldgaard Madsen et al. regarding the results of a study of 537,303 children, which concludes that there is a strong presumption that the MMR vaccination is a cause of autism.

On March 11, 2002, statements were given by the applicant's mother and Chief Physician Kai Erland Pedersen.

M has explained that she is the mother of the applicant and C, who are identical twins. She has, together with

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her spouse, two more boys who are older. The boys have received the MMR vaccination and have had no side effects other than a slight fever. The twins were small at birth, so she was a little concerned about their growth, but the children developed normally until the vaccinations on April 3, 1992. B was the more dominant of the twins. Before the vaccination, the girls were crawling and there was good contact. The nurse followed the normal examination and vaccination program, which is why she had no doubt that the girls should be MMR vaccinated. B was a little snotty at the time of the vaccination, but the doctor said it was nothing to worry about. She was told that after a week a slight fever could occur. She believes that the children were vaccinated on a Friday and, approx. 10 days later - on a Sunday - the girls had a fever of around 39. On Tuesday, the morning temperature was down to 37-38, but in the evening B was up to 39.3. C also had a high fever. An hour after B went to bed, she screamed very loudly and had a temperature of 40.3. She therefore contacted the emergency doctor and asked about the vaccination. The doctor said that there could be no connection, but he wanted to look at the girls. She drove them to the emergency center where they were examined by another doctor. After examining B's throat, the doctor said she had a throat infection and gave her some penicillin. The next day, she contacted her own doctor as she felt more comfortable with him. They only spoke on the phone and he prescribed a

different type of penicillin as the first could cause an upset stomach. Within a few days, both girls were fever-free and seemingly healthy. After 3-4 weeks, she realized that something was very wrong with B, as she didn't respond when called and you couldn't make eye contact with her. B would sit for hours picking up a toy and licking it. The twins stopped playing with each other and C started to become aggressive towards B, without B defending herself. They therefore suspected that she could not hear. The witness's parents had also noticed that something was wrong, as B could not support her legs as she had before. The witness contacted the doctor and they were initially referred to an ear specialist who only found a slight hearing loss in one ear. The hearing loss could not explain B's symptoms, so she was referred to the hearing clinic, but there was a long waiting time. She therefore got the doctor to refer B to the pediatric ward at Herning Central Hospital instead. Here they were taken seriously by doctor Malgorzata Pulczynska, and when the witness mentioned the vaccination, the doctor immediately went out and called the State's Serum Institute. It was agreed that B would be hospitalized for examination, which was done. However, it was not immediately possible to determine what was wrong with B, so contact was made with the child psychiatric department, which diagnosed infantile autism in November 1992. B, who is now 11 years old, now has beautiful language, but she is somewhat reserved. She has a little difficulty learning. The girls are in separate special classes in Herning, which they will attend until the end of 9th grade. B gets angry very easily, but is also easy to make happy again. She will probably never be able to manage on her own and will therefore probably have to live in a group home or similar when she grows up. C's form of autism - Asperger's Syndrome - is a milder form than B's. They concentrated so much on B that they probably overlooked C's problems for a long time, which only became apparent when she got a little older. When you have Asperger's syndrome, you are normally gifted, but you need a very safe environment. With a little support, C might be able to take care of herself.

Chief Physician Kai Erland Pedersen has explained that he has worked with child psychiatry for over 20 years. He has been a Chief Physician since 1982. Encephalitis is an inflammation of the brain that occurs after an infection with a bacterium or a virus. Encephalitis is most often caused by infection. The most common cause of encephalitis is the herpes virus, but in rare cases it has been caused by infection with the measles virus. The symptoms of encephalitis include high fever, loss of consciousness, seizures and paralysis. A child's inability to hear or react is not a sign of a disorder of consciousness, which can often be identified by asking, for example, the mother about the child's behavior. He hasn't seen encephalitis due to the superbug virus in the acute phase, but he has examined children with sequelae. He doesn't know how long the acute phase lasts, but it will probably be a few weeks. When infected with the superbug virus, the child will start with a cold and then develop a rash. Any encephalitis will only develop later. The ventricles are fluid-filled cavities in the brain. If some brain tissue has been lost, the cavity will be larger. Brain tissue can be lost due to encephalitis, for example. The ventricles are usually symmetrical in healthy children. Asymmetrical ventricles can be a sign of encephalitis, but are not enough to make a diagnosis. If you are examining a patient for encephalitis, a sample of spinal fluid will be taken to check for elevated protein. If this is the case, the antibody can be analyzed to find what kind of infection the patient has had. He does not know how long after the acute phase you can find any proteins. A foreign article describes a study in which 18 people with autism were examined. Of these, asymmetrical ventricles were found in 17 cases. He himself has studied a Greenlandic boy who developed autism following encephalitis. In that case, it was agreed that the boy had developed normally until he contracted an infection. The witness has examined two other patients where it was suspected that

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encephalitis was the cause of autism. He is also familiar with foreign literature describing cases of autism after encephalitis. In a highly respected 1999 article in CME Reviews, Professor Eric Hollander described how autism is caused by two factors: a genetic predisposition and a neurological disorder. Even if you are genetically predisposed to a disease, you are not sick because you can rule out the triggering factor. You can be genetically predisposed to autism without becoming ill. If you are not genetically predisposed, you cannot develop autism. The triggering factor can, for example, occur during pregnancy, birth itself or in the event of encephalitis. If you are not autistic from birth, it takes a neurological disorder to trigger autism. Most autistic people are autistic from birth, but it can be difficult to diagnose so early. Autism is a lack of full ability to share an experience with others. This manifests itself in a lack of eye contact, for example. B has classic autism. The witness has diagnosed C, who has a much milder form of autism, called Asperger's Syndrome. A person with Asperger's Syndrome develops language and is not mentally retarded. Since the twins are identical, they are genetically identical. Therefore, if the external influences are the same, the development will also be the same. He first saw B on July 17, 1992, when doctor Malgorzata Pulczynska called him to the children's ward where B had been admitted. He immediately suspected autism. His further investigations confirmed his suspicions. He did not suspect the cause of the autism at this point, but asked Malgorzata Pulczynska to perform the necessary physical examinations. A spinal tap is no more stressful for the child than a blood test. A spinal tap is performed to rule out serious disorders of the central nervous system, in particular meningitis and leukemia. He was not involved in reporting B's illness as a vaccination injury and only later learnt that this was suspected. The temporal relationship between the vaccination and the onset of the disease gives rise to considerations, but as a psychiatrist he cannot comment on the causal relationship. However, based on the temporal correlation and experience with the triple vaccine, he would certainly not rule out the possibility of a causal relationship. He assesses that B was healthy and well before the vaccine. He agrees with the Board of Forensic Medicine's answer to question 3, but encephalitis is not the most common cause of autism. He does not agree with the Board of Forensic Medicine's answers to questions 5 and 8, as the clinical findings should give cause for consideration. On September 29, 1993, during an examination of B, he found that she had reflex changes in one leg, but he has not been asked to provide the results of this examination for use in the case. The Board of Forensic Medicine should have obtained further information, and further examinations could have been carried out. He also does not agree with the Board of Forensic Medicine's answer to question 6, as the changes to the ventricles in autistic people are very small. He believes that the Board of Forensic Medicine's answer to question 7 is entirely incorrect, as it is documented that encephalitis can cause early infantile autistic syndrome. However, if the answer is to be understood to mean that encephalitis does not always cause early infantile autistic syndrome, he agrees with the Board of Forensic Medicine's answer. He agrees with the Board of Forensic Medicine's answer to question 9, but experience often shows that the random coincidences are nevertheless related.

In support of her main claim, *the applicant* submits that it has been established with reasonable probability that her condition - early infantile autistic syndrome - is a consequence of the vaccination on April 3, 1992. The expression "reasonable probability" in section 1 of the Vaccination Act must linguistically be perceived as a clearly more lenient requirement than "overwhelming probability" and must be assumed to mean that a connection cannot be excluded and that no requirement for a preponderance of probability can be made. In this connection, the High Court may conduct an in-depth review of the defendant's decision

regarding the causal link between the vaccination and the plaintiff's autism.

According to the evidence, it must be assumed that the applicant was fit and healthy and of an appropriate age before the vaccination, cf. the Board of Forensic Medicine's reply to question 1. Furthermore, it has been proven with overwhelming probability that the applicant developed a form of encephalitis 10-12 days after the vaccination, as the indications presented all unambiguously point in that direction. In support of this, the applicant has, inter alia, referred to the fact that approximately 10-12 days after vaccination, the applicant had symptoms similar to tonsillitis, including high fever (41 degrees on April 14, 1992), which is described as an indication of encephalitis. Furthermore, the plaintiff has referred to the mother's explanation of the plaintiff's condition, including that parents subsequently noticed disturbances of consciousness, seizures and motor problems, an article in a medical journal from 1973, the doctor on call's medical records, the detection of slight asymmetry of the lateral ventricles in connection with an examination at Skejby Hospital in 1993, the first resident physician Malgorzata Pulzcyńska's suspicion of encephalitis, see letter of January 4, 1993, and the reflex disorders. The Board of Forensic Medicine has also stated that the observations do not exclude that the applicant may have had encephalitis. In the applicant's opinion, it must therefore be assumed that

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the MMR vaccine (especially the measles vaccine) can cause brain inflammation (encephalitis).

Furthermore, the plaintiff has claimed that it is more than likely that encephalitis can trigger autism and has in this connection referred to several scientific articles etc. according to which a connection between encephalitis and autism cannot be denied. This assumption of a connection between the vaccination, encephalitis and autism is not immediately rejected by several of the doctors involved in the case.

The plaintiff's condition (early infantile autistic syndrome) after vaccination is a lifelong injury. There is no evidence that the plaintiff was hereditarily predisposed to autism. The fact that the twin sister has developed a milder form of autism is not evidence that the applicant was hereditarily predisposed.

It can also be noted that medical science in general does not categorically reject a possible link between the MMR vaccine and autism, but it shall be noted that there is currently no 100% certain proof of this assumption. However, the mother's information about how B's personality changed after the vaccination and the temporal relationship between the vaccination and the diagnosis of infantile autism make a causal link between the vaccination and the autism likely. The applicant has further argued that it is irrelevant whether the applicant may have been genetically predisposed to develop autism, as what matters is whether the vaccination triggered the autism. In this connection, the plaintiff has referred to the testimony of Chief Physician Kai Erland Pedersen. It can also be established that there is a temporal relationship between the vaccination and the injury, and this leads - in conjunction with the other circumstances - that the applicant has provided sufficient evidence of a causal link between the vaccine and the autism.

In support of the alternative claim, the claimant has argued that so much new information has emerged in the case in particular and the research in the area in general that this should result in the claimant's case being subjected to a new thorough examination by the National Board of Industrial Injuries or the Social Appeals Board.

In support of its claim, the defendant submits that the defendant's decision made at a meeting on December 18, 1996 is correct and that there is no basis for setting aside the defendant's expert assessment that the autistic disorder claimed by the applicant cannot be assumed with reasonable probability to have been caused by the MMR vaccination on April 3, 1992, cf. section 1(1) of the Vaccination Compensation Act.

Through the handling of these cases, the defendant has special experience in assessing whether the conditions of the Act are met. The defendant, with the assistance of specialized medical chief physicians, has made its decision based on an assessment of all the specific circumstances at hand, including the opinion obtained by the defendant from the Board of Forensic Medicine. There must therefore be a firm basis for setting aside the defendant's decision.

The burden of proving that there is a reasonable probability of causation rests with the claimant. In this connection, it is emphasized that the requirement of reasonable probability implies that there must be a preponderance of probability of causation, and that the requirement of reasonable probability cannot at any point in the line of evidence be interpreted as a presumption principle which implies that the defendant must disprove causation.

It is further submitted that the MMR vaccine cannot in itself cause autism. The MMR vaccination on April 3, 1992 has neither caused autism in the applicant nor has it caused such disorders in the applicant that could cause autism. Given that the applicant's twin sister has been diagnosed with Asperger's Syndrome, the reason why the applicant developed infantile autism is to be found in genetic factors rather than in the administered vaccinations. It is therefore disputed that the applicant was healthy before the vaccination.

It is hereby submitted that the medical examinations have not established with reasonable probability that the applicant developed encephalitis following the vaccination. The course of events after the vaccination does not indicate the presence of encephalitis, but must be regarded as a completely natural vaccination reaction. There is no other evidence that proves or even suggests encephalitis. Finally, the increase in temperature did not occur until about 10 days after the vaccination.

In this connection, the defendant has disputed that encephalitis can cause autism, but has not disputed that measles and the measles vaccine can cause encephalitis.

It is further disputed that the temporal relationship between the vaccination and the onset of the disorder is sufficient to establish a reasonable probability of causation, or would lead to a presumption of causation with the consequence that the defendant must disprove causation.

It is argued that the fact that the MMR vaccination is a free offer that anyone can opt out of after assessing the risks does not relax the requirement for causality, let alone increase the obligation to pay compensation.

In assessing whether there is a sound basis for setting aside the defendant's decision, only the medical knowledge available at the time of the defendant's decision shall be taken into account. Subsequent examination results, including reassessments of studies already carried out,

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which may justify assumptions about causality, cannot affect the validity of the defendant's decision, but may, if necessary, justify an application to the National Board of Industrial Injuries for an administrative reopening of the case. However, the latest research and the latest articles in medical journals have not demonstrated a link between the MMR vaccine and autism - on the contrary. The evidence presented during the trial cannot result in a change in the defendant's decision either.

The High Court's reasoning and result:

In deciding the case, the High Court has based its judgment on the fact that the term "Reasonable probability" in section 1 of the Act on Compensation for Vaccination Injuries must be understood to mean that it contains a relaxation of the usual requirements for proof of causality in a compensation case, but that there must be an overwhelming probability (more than 50%) that the injury was caused by the vaccination.

According to the Board of Forensic Medicine's answer to question 1 in the first statement of February 6, 1996, it must be assumed that the plaintiff in all probability had been completely normally developing up to the time of vaccination.

In the first statement in the answer to question 3, the Board of Forensic Medicine stated that the available information cannot establish with reasonable probability that the applicant developed encephalitis as a result of the MMR vaccination. In the last statement of October 24, 2002, the Board of Forensic Medicine stated that the reflex disorders found in the right leg may be compatible with, but need not necessarily be, an expression of a prior previous brain injury.

These assessments are not incompatible with the assessment of Chief Physician pediatric Psychiatrist Ingelise Sillesen in her statement of February 11, 1994, after which Ingelise Sillesen, as the disease picture has developed, believes that there is reasonable suspicion that the plaintiff may have had encephalitis, but whether the encephalitis was caused by the vaccination, the Chief Physician cannot comment on, except that there is a "certain probability" of this due to the temporal relationship.

In the first statement, the Board of Forensic Medicine stated that permanent psychological damage may occur after encephalitis, but only rarely in the form of the present condition of infantile autism. In the second statement of July 2, 1998 in response to question 7, the Board of Forensic Medicine stated that there is no certain evidence that encephalitis causes early infantile autistic syndrome. After an overall assessment of the medical information provided, including in particular the Board of Forensic Medicine's answers to the questions asked, and the other available information, including the information on the correlation between the vaccination and the development of the disease and the explanations given, the High Court does not find that there is a reasonable probability that the applicant's autism is caused by the vaccination and a resulting encephalitis. Nor does the latest article in a medical journal on MMR vaccination and autism indicate that there is a reasonable probability that MMR vaccination can cause autism.

As there is no basis for upholding the plaintiff's alternative claim, the High Court upholds the defendant's claim for acquittal.

Neither party shall pay the legal costs of the other party or the treasury.

Supreme Court

Supreme Court judgment.

In a previous instance, the 13th district of the Western High Court handed down a judgment on March 12, 2003.

Five judges participated in the judgment: Poul Sørensen, Per Sørensen, Poul Søgaard, Jytte Scharling and Jon Stokholm.

Claims

The appellant, B, has principally claimed that the respondent, the National Social Appeals Board, should be ordered to recognize that her disorder (early infantile autistic syndrome) shall, with reasonable probability, be assumed to be a consequence of the vaccination she received on April 3, 1992 against measles, mumps and rubella (MMR vaccination), among other things, and is thus covered by the Vaccination Compensation Act. In the alternative, she has claimed that the case be referred back to the National Social Appeals Board for reconsideration.

The National Social Appeals Board has requested confirmation.

Before the Supreme Court, the appellant has referred to further medical literature.

The Supreme Court's reasoning and result

As a preliminary point, it should be noted that the first part of the appellant's main claim must be regarded as a statement in law in support of the second part of the claim and cannot therefore be included as part of the claim.

For the reasons stated by the High Court, and because what has been presented to the Supreme Court cannot lead to a different result, the Supreme Court upholds the judgment.

For it is recognized as correct:

The High Court's judgment is upheld.

The Danish Treasury must pay DKK 50,000 in legal costs to the Supreme Court within 14 days of the Supreme Court's judgment.

U.2005.2151H

Ikke erstatningsansvar for det offentlige efter vaccinationserstatningsloven, da lidelse ikke kunne anses for forårsaget af MFR-vaccination.*Erstatning uden for kontraktforhold 111.2, 141.9, 21.2 og 21.9 - Forvaltningsret 24.9.*

- ♦ Den 3. april 1992 blev barnet B, der da var knap 1½ år gammel, vaccineret mod mæslinger, fåresyge og røde hunde (MFR-vaccination). 10 dage efter vaccinationen fik B høj feber, der varede i ca. 5 dage. Efter sygdomsperioden blev B's motorik usikker, og hendes sproglige udvikling gik tilbage. Det viste sig, at B var kommet til at lide af infantil autisme. B's forældre, F og M, krævede erstatning i henhold til vaccinationserstatningsloven, men såvel Arbejdsskadestyrelsen som Ankestyrelsen, A, der forinden havde indhentet en udtalelse fra Retslægerådet, afslog erstatning. A henviste herved til, at lidelsen - uanset det tidsmæssige sammenfald mellem vaccinationen og sygdommens debut - ikke med rimelig sandsynlighed var forårsaget af vaccinationen. F og M indbragte sagen for landsretten, under hvis behandling der blev indhentet yderligere udtalelser fra Retslægerådet. Efter en samlet vurdering af de lægelige oplysninger i sagen, herunder diverse lægevidenskabelige artikler, fandt landsretten ikke, at der var rimelig sandsynlighed for, at B's autisme var forårsaget af vaccinationen, og frifandt A. Højesteret stadfæstede dommen i henhold til grundene.¹

H.D. 19. april 2005 i sag 167/2003 (2. afd.)

B ved værgerne F og M (adv. Bjarne E. Bødtker, Skjern, e.o.) mod Ankestyrelsen (Km.adv. v/adv. Henrik Nedergaard Thomsen, Kbh.).

Vestre Landsret***Vestre Landsrets dom 12. marts 2003 (13. afd.)***

(Eva Staal, Ole Græsbøll Olesen, Helle Korsgaard Lund-Andersen (kst.)).

Under denne sag, der er anlagt den 27. juni 1997, har sagsøgeren, B, ved værgerne F og M, påstået sagsøgte, Den Sociale Ankestyrelse, tilpligtet at anerkende, at sagsøgerens lidelse (tidligt infantilt autistisk syndrom) må antages at være en følge af den vaccination, sagsøgeren modtog den 3. april 1992 mod mæslinger, fåresyge og røde hunde (MFR-vaccination), og dermed omfattet af vaccinationserstatningsloven. Sagsøgeren har nedlagt en subsidær påstand om, at sagen - for det

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tilfælde, at den principale påstand ikke tages til følge - hjemvises til fornyet behandling i Arbejdsskadestyrelsen/Den Sociale Ankestyrelse.

Sagsøgte har påstået frifindelse.

Sagsøgeren er født den 31. december 1990 og har tvillingsøsteren C.

Der er meddelt sagsøgeren fri proces, og der er retshjælpsforsikringsdækning.

Den 18. december 1996 traf sagsøgte følgende afgørelse efter at have genoptaget sagen, hvor der tidligere var truffet afgørelse af Arbejdsskadestyrelsen den 28. marts 1994 og af sagsøgte den 19. oktober 1994:

»...

Den anmeldte lidelse i form af infantil autisme kan ikke anerkendes som en skade efter MFR-vaccination, der er omfattet af lov om erstatning for vaccinationsskader.

Begrundelsen er, at det ikke kan anses for godtgjort, at lidelsen med rimelig sandsynlighed må antages at være forårsaget af MFR-vaccination foretaget den 3. april 1992, jf. lovens § 1, stk. 1.

Ankestyrelsen har lagt vægt på, at selv om der er tale om et tidsmæssigt sammenfald mellem vaccinationen og sygdommens debut, har de foretagne undersøgelser under indlæggelse på Herning Centralsygehus i sommeren 1992 ikke med rimelig sandsynlighed godtgjort, at Deres datter udviklede hjernebetændelse i tilslutning til vaccinationen, ligesom der ikke under den febrile periode, der begyndte 10 dage efter vaccinationen har været kliniske tegn på hjernebetændelse.

Ankestyrelsen har også lagt vægt på, at varige psykiske skader, som vil kunne forekomme efter en hjernebetændelse (encephalitis), kun sjældent forekommer i form af infantil autisme, og at der ikke for tiden er lægevidenskabeligt belæg for at antage en sammenhæng mellem MFR-vaccination og autisme.

For så vidt angår Deres spørgsmål om ikke den infantile autisme kan være opstået som følge af vaccinationen uden forudgående hjernebetændelse skal Ankestyrelsen henvise til Retslægerådet svar af 6. februar 1996. Ankestyrelsen er som anført ovenfor enig i Retslægerådets udtalelse.

For så vidt Deres advokat har henvist til amerikanske undersøgelser offentliggjort i 1973 skal Ankestyrelsen bemærke, at resultaterne ikke kan overføres til det danske vaccinationsprogram, der blev iværksat i 1987. I det omfang der i refererede undersøgelser i øvrigt er anvendt vacciner, der er forskellige fra de vacciner, der anvendes i Danmark, vil der heller ikke være grundlag for at anvende resultater fra udenlandske undersøgelser.

Ankestyrelsen fastholder således sin afgørelse af 19. oktober 1994, meddelt den 1. november 1994.

Grundlaget for afgørelsen:

...

Afgørelse af, om den nødvendige grad af sandsynlighed, jf. ordlyden i § 1, stk. 1, i lov om erstatning for vaccinationsskader, er til stede, beror på en vurdering af det enkelte tilfældes faktiske forhold set i lyset af den til enhver tid værende lægelige viden og erfaring.

En bevisregel kan derfor ikke udfylde eller erstatte denne lægelige viden og erfaring, der er forudsætningen for anerkendelse af en sygdom som erstatningsberettigende.

Det fremgår af anmeldelse af 17. september 1993 fra Børneafdelingen på Herning Centralsygehus, at Deres datter den 3. april 1992 blev vaccineret mod mæslinger, fåresyge og røde hunde. 10 dage efter vaccinationen fik Deres datter høj feber over 40 grader. Tilfældet varede 5 dage, hvorefter feberen faldt. Efter sygdomsperioden blev Deres datters motorik usikker, hun virkede mere hypoton (slap i musklerne), og hendes sproglige udvikling gik tilbage, ligesom hun virkede indelukket, og var svær at få øjenkontakt med.

Deres datters helbredsmæssige forhold er beskrevet bl.a. i erklæring af 24. marts 1993 fra Børneafdelingen på Herning Centralsygehus, erklæring af 16. december 1993 fra overlæge Kai Erland Pedersen, Børnepsykiatrisk Afdeling på Centralsygehuset i Herning

¹ FT 1971/72, Forhandlingerne sp. 763, FT 1971/72, till. B, sp. 2242, FT 1995/96, till. A, s.1377, FT 2002/03, till. A, s. 6997, og Bo von Eyben: Patientforsikring (1993), s. 83 ff.

samt erklæring af 11. februar 1994 fra adm. overlæge Ingelise Sillesen, Børnehospitalet i Risskov.

Det fremgår heraf, at Deres datter lider af infantil autisme.

Herudover har Arbejdsskadestyrelsen indhentet en udtalelse af 13. september 1993 fra overlæge F. Karup Pedersen, Rigshospitalets Børneafdeling. I denne udtalelse er anført, at encephalitis (hjernebetændelse) efter MFR-vaccination er beskrevet, men langt sjældnere end efter naturlig infektion med mæslinge-, fåresyge- og røde hunde-virus. Hvorvidt den febrile episode, der optrådte 10 dage efter MFR- og Di-Te-Pol-vaccinationen i 15 måneders alderen var ledsaget af encephalitis, kan ikke sikkert vurderes. De undersøgelser med henblik herpå, der er foretaget på børneafdelingen på Herning Centralsygehus, er negative, men undersøgelserne er først foretaget i juli måned, altså 3 måneder efter vaccinationen. Et negativt resultat på dette tidspunkt udelukker ikke, at der kan have været tale om en forudgående encephalitis.

Det er videre udtalt, at patienter med infantil autisme ofte har lettere tegn på organisk hjerneskade, fx. i form af eeg-forandringer eller fund ved psykologiske tests, der kunne tyde på organisk hjernepåvirkning. Det kan således ikke afvises, at en eventuel encephalitis vil kunne være medvirkende årsag til udvikling af en autistisk tilstand. Den tidsmæssige sammenhæng kunne tale for en forbindelse mellem vaccination,

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efterfølgende cerebral påvirkning og autisme, men kan naturligvis ikke betragtes som noget bevis, ligesom der altså som beskrevet ikke ved de foretagne undersøgelser er fundet holdepunkter for, at en hjernebetændelse har været til stede. De negative undersøgelser kan imidlertid ikke udelukke, at dette kan have været tilfældet.

I erklæringen af 16. december 1993 fra overlæge Kai Erland Pedersen er udtalt, at det ikke er muligt at have sikker viden om en direkte sammenhæng mellem den specifikke vaccine, der har været anvendt, og Deres datters lidelse.

I udtalelse af 11. februar 1994 fra overlæge Ingelise Sillesen, Børnehospitalet, er anført, at som Deres datters sygdomsbillede har udviklet sig med høj feber 10 dage efter vaccinationen, medtaget almentilstand og herefter motoriske problemer i form af nedsat tonus (muskelspænding) og usikker gang, sproglig tilbagegang, manglende øjenkontakt og ændret adfærd, er det vanskeligt at forestille sig andet end, at der må have været tale om en cerebral (»hjerne«) påvirkning, enten denne er forårsaget af MFR-vaccinen eller ej.

Det er videre oplyst videre, at der ikke er en enkelt ætiologisk forklaring på infantil autisme, men der er i dag udbredt enighed om, at infantil autisme er biologisk betinget, og at symptomerne er forårsaget af en cerebral dysfunktion (funktionsforstyrrelse i hjernen). En genetisk disposition (sårbarhed) synes at spille en vis rolle i nogle tilfælde. Af årsager iøvrigt kan nævnes kromosomale- og metaboliske (»stofskifte«) lidelser, cerebrale infektioner og andre sygdomme i centralnervesystemet.

Efter Ankestyrelsens afgørelse den 1. november 1994 har advokat Bjarne E. Bødtker i et brev af 28. november 1994 for så vidt angår kravet om bevis for årsagssammenhæng jf. § 1, stk. 1, i lov om erstatning for vaccinationsskader, generelt henvist til lovens formulering »rimelig sandsynlighed«.

Advokaten har påpeget, at denne formulering indikerer, at kravet om sandsynlighed for årsagssammenhæng er i den lave ende af »sandsynlighedsskalaen«, og at Arbejdsskadestyrelsen for nylig i en sag om idiopatisk trombocytopenisk purpura anerkendte årsagssammenhængen »da en årsagssammenhæng ikke kunne udelukkes«.

Den samme argumentation og konklusion kan efter advokatens opfattelse benyttes i nærværende sag, såfremt Ankestyrelsen ikke umiddelbart er enig i, at den rimelige sandsynlighed om årsagssam-

menhæng fuldt ud er dokumenteret, ifølge de allerede foreliggende speciallægeerklæringer fra overlæge Kaj Erland Pedersen og overlæge Ingelise Sillesen.

Advokaten har i øvrigt oplyst, at der fortsat søges i både ind- og udland angående lignende tilfælde af sammenhæng mellem MFR-vaccinen og efterfølgende hjerneskader (autisme og lignende), og at Ankestyrelsen løbende vil blive underrettet om disse undersøgelser.

Ankestyrelsen har efterfølgende indhentet journaloplysninger fra lægehuset i Tarm samt sygehusjournal fra Herning Centralsygehus.

Af disse oplysninger fremgår bl.a., at B siden hun var helt lille har været lang tid om at spise. I august 1991, hvor hun var omkring 9 måneder gammel, var hun henvist til Børneafdelingen på Herning Centralsygehus på grund af spiseproblemer ved overgang til skemad.

Ved Boelprøve i 9 måneders alderen havde sundhedsplejersken mistanke om hørenedsættelse hos B og hendes tvillingsøster.

Ca. 10 dage efter vaccinationen den 3. april 1992 fik begge tvillinger høj feber. Vagtlægen mente, at der var tale om halsinfektion, og begge tvillinger blev sat i penicillinbehandling.

Der er foretaget MPU-vurdering på Herning Centralsygehus i juli 1992, hvor B er bedømt til at befinde sig på 1 års niveau med hensyn til grovmotorik, finmotorik, følesans og syn. Det vurderes ved undersøgelsen, at B ikke synes at reagere på verbal kontakt.

Stimulation med Wabletoner, Ewingsrangler og Boelprøve foretaget i august 1992 på Herning Sygehus, har vist normal hørelse på højre øre, mens der er langsommere og usikker reaktion på venstre øre.

B's lidelse er i erklæring af 16. november 1992 fra overlæge Kai Erland Pedersen, beskrevet som klassisk tidligt infantilt autistisk syndrom.

Under genoptagelsen af sagen har Ankestyrelsen indhentet en udtalelse fra Retslægerådet.

På Ankestyrelsens spørgsmål 1, om »hvordan vurderes B's helbredstilstand og udvikling frem til MFR-vaccination den 3. april 1992, herunder anmodes om Retslægerådets vurdering af betydningen af, at den omkring 1. august 1991 (i 7 måneders alderen) udviklede spisevægring hos barnet« har Retslægerådet den 6. februar 1996 udtalt:

»Ud fra de foreliggende journaloplysninger fra børneafdelingen, Herning Sygehus har barnet haft forbigående spiseproblemer sommeren 91. Trivslen dog ikke påvirket på noget tidspunkt. Problemerne svandt efter vejledning og ved vurdering 9.10.91 fandtes barnet i orden og afsluttedes. Ud fra disse oplysninger, og journaloplysningerne ved indlæggelsen 12.07.92, må det antages, at barnet efter al sandsynlighed har været helt normalt udviklet frem til vaccinationstidspunktet 03.04.92. Den forbigående spisevægring kan ikke ud fra det foreliggende tillægges nogen betydning i denne sammenhæng.«

På Ankestyrelsens spørgsmål 2, om det kan have haft betydning for udviklingsforløbet, at barnet den 24. marts 1992 havde langvarig og febril sinuitis purulente, har Retslægerådet svaret:

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»Af et yderst kort notat den 24. marts 1992, formentlig stammende fra egen læges (G. Hansen, Tarm) journal, fremgår, at patienten på daværende tidspunkt led af langvarig og febril sinuitis purulenta. Denne sættes i behandling med abbotycin 140 mgx 3 dgl. Journalnotatet tillader ikke vurdering af patientens tilstand på det pågældende tidspunkt. Ud fra det foreliggende har Retslægerådet derfor ingen mulighed for at udtale sig om den pågældende sinuits mulige betydning for udviklingsforløbet.«

På Ankestyrelsens spørgsmål 3, »Kan B med rimelig sandsynlighed antages at have udviklet hjernebetændelse (encephalitis) som

en følge af MFR-vaccination? Der er under indlæggelse på Børneafdelingen, Centralsygehuset i Herning i juli/august 1992 foretaget »rygmarvsprøve« (spinalundersøgelse) hos B. Denne er undersøgt specielt med henblik på forekomst af æggehvidestofforhøjelse, som det generelt ses ved hjernebetændelse »encephalitis«. Retslægerådet bedes udtale sig om, hvorvidt de målte værdier taler imod, at B har haft hjernebetændelse«, har Retslægerådet udtalt:

»De foretagne undersøgelser på børneafdelingen, Herning Sygehus godt 3 mdr. efter vaccinationen viser normal spinalvæske uden celler og med normalt protein og uden titre for morbilli, parotitis og rubella. CT-scanning af cerebrum er ligesom øjenundersøgelsen normal. Hæmatologiske kvantiteter, lever- og væsketal er alle ligeledes normale. Blodtitre for morbilli og rubella er pos. med hensyn til IgG, men der er ingen påviselige titre for parotitis. Metabolisk screening for aminosyrer og flygtige syrer i urinen er negativ, lysosomale enzymer ligeledes negative. MR-scanning af cerebrum den 01.03.93 er også normal udover en let asymmetri af sideventriklerne - hvilket efter Retslægerådets vurdering må vurderes som formentlig betydningsløst i sammenhængen. Endelig er høreundersøgelse den 23.03.93 normal.

De foretagne undersøgelser kan således ikke bekræfte, at patienten har haft en encephalitis i tilslutning til vaccinationen. På den anden side taler de ikke imod, at patienten kan have udviklet en encephalitis, idet en sådan tilstand i mange tilfælde ikke giver anledning til varige specifikke ændringer i de foretagne laboratorieundersøgelser. Man kan således eksempelvis godt have (have haft) encephalitis uden påviselige ændringer i æggehvideofferne i spinalvæsken. I sådanne tilfælde er man henvist til at stille diagnosen ude fra de rent kliniske symptomer, med den usikkerhed dette indebærer.

Efter det oplyste, har der imidlertid ikke været observeret nogle af de symptomer, der sædvanligvis ses ved encephalitis, såsom bevidsthedsforstyrrelser, kramper eller lammelser. Den kortvarige febrile tilstand omkring 10 døgn efter vaccinationen, må betragtes som en forventelig vaccinationsreaktion. Der kan således ikke med rimelig sandsynlighed godtgøres, at patienten har udviklet hjernebetændelse som følge af MFR-vaccination.

Hertil skal tilføjes, at der ikke Retslægerådet bekendt foreligger nogen sikre oplysninger i den internationale litteratur for en sammenhæng mellem MFR-vaccination og autisme. Det forhold, at der ikke kan påvises anden begivenhed end MFR-vaccinationen, som ud fra et tidsmæssigt sammenfald teoretisk kunne tænkes at have årsagssammenhæng med patientens symptomer, gør ikke, at dette kan tages som bevis for en sådan sammenhæng, idet der alene kunne være tale om et tilfældigt sammenstød.

Endelig skal anføres, at der efter encephalitis, som der i den aktuelle sag ikke er fundet rimelig sandsynlighed for, vil kunne forekomme varige psykiske skader, men kun sjældent i form af den foreliggende tilstand infantil autisme«.

På Ankestyrelsens spørgsmål 4, »Hvis spørgsmål 3 besvares bekræftende: Kan en psykisk lidelse hos B (diagnosen infantil autisme er stillet) med rimelig sandsynlighed antages at være en følge af MFR-vaccination«? har Retslægerådet svaret: »Eftersom spørgsmål 3 ikke kan besvares bekræftende, bortfalder spørgsmål 4«.

Advokat Bjarne Bødtker har i brev af 20. februar 1996 forespurgt, om ikke infantil autisme kan være opstået efter vaccinationen uden forudgående hjernebetændelse, og om Retslægerådet ikke finder det tankevækkende, at sunde og raske børn udvikler hjerneskade i tilknytning til en MFR- og Di-Te-Pol vaccination, og i den forbindelse overveje om en eventuel sammenhæng ikke kan udelukkes.

Advokaten har desuden i brev af 28. november 1996 anført, at det er hans opfattelse, at bevisbyrden for at de konstaterede skader ikke skyldes vaccinationerne, burde påhvile det offentlige, når der i sagerne vedr. B og et andet barn er dokumenteret tidsmæssigt

sammenfald, og især fordi børnene også efter Retslægerådets opfattelse var sunde og raske inden vaccinationerne.

De og advokaten har foreløbigt følgende bemærkninger til Retslægerådets udtalelse af 6. februar 1996: Retslægerådet skriver, at der ikke hos B har været observeret nogle af de symptomer, der sædvanligvis ses ved encephalitis, såsom bevidsthedsforstyrrelser, kramper eller lammelser. Hvorfor tror Retslægerådet, at pædiaterne på børneafdelingen på Herning Centralsygehus udsatte en halvandet år gammel pige for en rygmarvsprøve, hvis ikke det var på mistanken om, at der havde været encephalitis. Efter Deres og advokatens opfattelse er anmeldelsen en lang manifestation om, at Deres datter har været udsat for en hjernemæssig påvirkning på det pågældende tidspunkt. Advokaten citerer fra anmeldelsen: 15 måneder gammel vaccineret for MFR og De-Te-Pol sammen med sin tvillingsøster. 10 dage efter vaccinationen kom der høj feber, over 40 grader. Pigen var

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medtaget de næste 5 dage, feberen faldt spontant, men barnet blev aldrig sig selv igen. Man kunne ikke få kontakt med hende. Hendes udvikling gik i stå og på nogle områder næsten tilbage. Hun gik tilbage til blendet kost, skulle mades, kunne ikke længere selv drikke af kop. Hun virker mere hypoton. Man havde svært ved at lokke hende til at gribe efter legetøj eller rulle om på maven, men man kan alligevel få hende til at kravle på gulvet, sidder pænt og leger, og rejser sig ved møbler. Gangen er meget usikker, og hun virker meget ustabil i hofterne. Man har meget svært ved at få øjenkontakt med hende, hun virker indelukket, og hun er ikke interesseret i mennesker, men kun i ting. Hendes måde at lege med legetøj på, er at sidde på gulvet og slikke dem.

Advokaten har videre spurgt, hvad mener Retslægerådet det er, når barnet »virker mere hypoton, gangen usikker, ustabil i hofterne«? Tygge- synkefunktion er jo også påvirket? Hvis ikke det, at al kontakt med barnet pludselig er umulig, er bevidsthedsforstyrrelser, hvad er det så?

MR-scanning har vist, at Deres datter har en let asymmetri af sideventriklerne. At dette af Retslægerådet vurderes betydningsløst er efter advokatens opfattelse ikke korrekt, hvilket begrundes med henvisning til to artikler. 1. JAMA 26.3.1973 og 2. Varied MR appearance of autism, af Martha Anne Nowell o.s.v. Fra artiklen i JAMA ved De, at der især i vintermånederne er hjernebetændelse-risiko efter vaccination med mæslingevirus, som efterlader blivende neurologiske forstyrrelser fra let opmærksomhedsforstyrrelser og motorisk uro til dyb mental retardation, og at hjernebetændelse typisk opstår ca. 6-11 dage efter vaccinationen. (Hos Deres datter startede feberen på 10. dagen). Fra artiklen i det amerikanske psykiatriske tidsskrift ved De, at der hos 18 autistiske patienter er let asymmetri af de laterale ventrikler. I denne henseende adskiller autistiske patienter sig ikke fra patienter med andre neurologiske sygdomme. Deres datters venstre hjernehulrum i nakkelappen er en smule større end det modsidige.

Retslægerådet og Ankestyrelsen bør derfor, efter advokatens opfattelse, revurdere sagen ud fra ovennævnte bemærkninger og de vedlagte artikler.

Ved behandling af sagen i Ankestyrelsen har der deltaget rådgivende speciallæger.«

I tilknytning til sagsfremstillingen i sagsøgtes afgørelse fremgår det af et journalnotat af 23. juni 1992 fra egen læge, læge Georg Hansen, at moderen, M, fandt, at B pludselig var standset i sin udvikling, og at B »sidder som i en glasklokke«.

Det fremgår af en skrivelse af 4. januar 1993 fra 1. reservelæge Malgorzata Pulczynska til Skejby Sygehus, MR-scanning centret, at man havde mistanke om encephalopati efter vaccination.

Af erklæringen af 16. december 1993 fra overlæge Kai Erland Pedersen fremgår bl.a. yderligere:

»...

Af væsentligt nyere materiale har vi gennemlæst en beretning fra 1989 fra det tyske Monatschrift für Kinderheilkunde, en artikel, som findes i dette tidsskrift, bind 137, hæfte 8 fra side 440 til side 446, hvor forfatterens navn er K.E.v. Mühlendahl.

I artiklen beskrives over en 3 års periode 6 børn, hvor der tidsmæssigt er et sammenfald mellem mæslinge/fåresygevaccination og pædiatrisk sygdom.

...

Artiklen indeholder litteraturoversigt, hvoraf det fremgår, at der på daværende tidspunkt var beretninger om 38 børn med idiopathisk trombocytopenisk purpura efter vaccination mod mæslinger og fåresyge, mens der var beretninger om 8 andre børn med meningisme.

Der gøres opmærksom på, at incidensen af cerebral affektion efter vaccination er 13 gange højere end den ellers ventede hyppighed (meningitis m.v., som ville være optrådt efter smitte med mæslinger).

...

Om den direkte sammenhæng mellem den til barnet anvendte specifikke vaccine og det tidligt infantile autistiske syndrom, som meget vel kan være en følgetilstand til en tidlig encephalitis, kan det på de foreliggende oplysninger ikke være muligt at have nogen sikker viden.

Man kan dog ikke undgå at hæfte sig ved det tidsmæssige forløb (fire af de omtalte meningismer optræder mellem 2. og 48. dag efter vaccinationen, en på 4. dagen, en på 26. dagen, en på 20. dagen og en på 5. dagen).

Endvidere skal jeg anføre, at vi fra en ikke meget gammel svensk undersøgelse ved, at det er de færreste børn med tidligt infantilt autistisk syndrom, hvor der ikke lader sig påvise et hjerneorganisk substrat (Steffenburg i Developmental Medicine and Child Neurology, 1991, bind 33, side 495).«

I afslutningen på udtalelsen af 11. februar 1994 fra overlæge, speciallæge i børnepsykiatri Ingelise Sillesen hedder det:

»...

Jeg mener ikke, at der er noget, der taler imod, at pigens nuværende autistiske tilstand kan være forårsaget af en evt. encephalitis på det pågældende tidspunkt. Som sygdomsbilledet har udviklet sig, synes jeg, der er begrundet mistanke om, at pigens kan have haft en encephalitis, men om encephalitten er forårsaget af vaccinationen, kan jeg naturligvis ikke udtale mig om udover, at der er en vis sandsynlighed herfor på grund af det tidsmæssige sammenfald.»

Det fremgår af en anmeldelse af 21. oktober 1997 fra overlæge Kai Erland Pedersen til Statens Seruminstitut

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vedrørende febrilia efter vaccination med efterfølgende udviklingsforstyrrelse, at sagsøgerens tvillingsøster C 11 dage efter vaccinationen havde 40 graders feber, at C har fået konstateret Aspergers Syndrom, og at det ikke kan udelukkes, at dette har samme årsag som sagsøgerens autistiske syndrom.

Efter sagens anlæg har Retslægerådet den 2. juli 1998 afgivet følgende svar på tre supplerende spørgsmål:

»...

Spørgsmål 5.

I Retslægerådets svar på spørgsmål 3 oplyses det, at »Efter det oplyste, har der imidlertid ikke været observeret nogle af de symptomer, der sædvanligvis er ved encephalitis, så som bevidsthedsforstyrrelser, krampes eller lammelser.« Retslægerådet bedes i den forbindelse oplyse, om man ved denne besvarelse har taget hensyn til bl.a. 1. reservelæge Malgorzata Pulczynska's anmeldelsesskrivelse af d. 17/9-1992 til Arbejdsskadestyrelsen (underbilag til bilag

62 til stævningen), hvor der bl.a. er beskrevet bevidsthedsforstyrrelser, usikker gang, ustabilitet i hofterne og i modsat fald, om disse oplysninger og/eller sagens akter iøvrigt giver anledning til at ændre svaret på spørgsmål 3.

1. reservelæge Malgorzata Pulczynska's anmeldelse til Arbejdsskadestyrelsen af 17.09.92 har indgået i det samlede grundlag for vurderingen af patienten og giver ikke anledning til at ændre svaret på det oprindelige spørgsmål 3.

Spørgsmål 6.

Retslægerådet bedes efter gennemgang af bilag 63 og 64, artikler i henholdsvis JAMA og i Magnetic Resonance Imaging begrunde, hvorfor man finder det betydningsløst, at B (sagsøger) har en let asymmetri af hjernens sideventrikler, når man fra artiklen i JAMA får oplyst, at der især i vintermånederne er en encephalitisrisiko efter vaccination mod mæslinger, som efterlader blivende neurologiske skader fra let opmærksomhedsforstyrrelser og motorisk uro over til dyb mental retardation. Samme artikel viser, at den pågældende type hjernebetændelse typisk opstår 6-11 dage efter vaccination.

Den lette asymmetri af hjernens sideventrikler er vurderet »som værende formentlig betydningsløs i sammenhængen«, idet forandringerne er ganske lette, og det kan tilføjes, sandsynligvis udtryk for en medfødt normal variation, eftersom der ikke er påvist andre tegn til anatomisk hjerneskade.

Spørgsmål 7.

Retslægerådet bedes be- eller afkræfte, at MFR-vaccination kan medføre hjernebetændelse og at hjernebetændelse kan medføre tidligt infantilt autistisk syndrom.

MFR-vaccination formodes i sjældne tilfælde at kunne være en årsag til hjernebetændelse. Derimod findes ingen sikre holdepunkter for, at hjernebetændelse medfører tidligt infantilt autistisk syndrom.

...«

Den 20. januar 1999 har Retslægerådet besvaret to yderligere spørgsmål således:

»...

Spørgsmål 8:

I tilknytning til Retslægerådets besvarelse af spørgsmål 5, ønskes konkretiseret, hvorfor Retslægerådet ikke finder, at de beskrevne bevidsthedsforstyrrelser, usikker gang, ustabilitet i hofterne m.v. kan være sikre kliniske tegn på hjernebetændelse, idet disse kliniske tegn var direkte årsag til diverse undersøgelser af sagsøger - herunder bl.a. en rygmarvsprøve. Hvis Retslægerådet fastholder, at disse objektive kliniske observationer, jvf. 1. reservelæge Malgorzata Pulczynska's skrivelse af d. 17/9-1992 er »betydningsløse« i forhold til sagsøgers konstaterede autisme, bedes Retslægerådet oplyse, hvorledes disse kliniske observationer ellers skal tolkes.

I 1. reservelæge Malgorzata Pulczynska's skrivelse af 17.09.92 er der ikke anført noget om bevidsthedsforstyrrelser. Derimod er der anført »gangen er meget usikker, og hun virker meget ustabil i hofterne«. Dette kortfattede notat er ikke ledsaget af nogen egentlig beskrivelse af abnorme objektive fund, og bemærkningen om ustabil gang kan ikke anses for at være et specifikt symptom tyden- de på en specifik sygdom. Notatet giver heller ikke grundlag for, at Retslægerådet nærmere kan uddybe, hvad årsagen kunne være til, at gangen blev beskrevet som usikker med ustabilitet i hofterne.

Spørgsmål 9:

I tilknytning til Retslægerådets besvarelse af spørgsmål 7, hvor man anfører, at der ingen sikre holdepunkter findes for, at hjernebetændelse kan medføre tidligt infantilt autistisk syndrom, vedlægges som bilag 71 artikel fra Developmental Medicine and Child Neurology fra 1991, side 495-511, skrevet af Susanne Steffenberg, M.D. i børnepsykiatri, tilknyttet Göteborg Universitet i Sverige. I artiklen beskriver forfatteren bl.a. forskellige årsager til autisme.

På side 501 tabel 2 nævnes herunder et barn med autismlignende forstyrrelser, hvor årsagen er hjernebetændelse, og på side 502 tabel 4 nævnes et barn med autisme, hvor man har fundet forhøjet protein i en rygmarsprøve, hvilket forfatteren opfatter som tegn på, at årsagen til barnets autisme er en langsom hjernebetændelse.

Som bilag 71A vedlægges artikel fra Schizophrenia Bulletin bind 7 nr. 3 side 413 fra 1981, hvor der henvises til en anden artikel i Archives of disease childhood bind 50 side 115-119, 1975, af Revenius, t.n. og andre, hvor der bl.a. også er beskrevet hjernebetændelse som direkte årsag til tidligt infantilt autistisk syndrom.

Retslægerådet bedes herefter revurdere spørgsmål om, hvorvidt der alligevel findes et forholdsvist sikkert

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holdepunkt for, at hjernebetændelse *kan* medføre autisme.

Referencer til litteraturen er alle referencer til enkeltstående kasuistiske tilfælde, hvor coincidens mellem forskellige begivenheder kan være et tilfælde eller kan have en mulig årsagssammenhæng. Men disse enkeltstående tilfælde tillader ikke en nærmere analyse af sandsynligheder eller hyppigheder.

Den anførte litteratur giver således ikke Retslægerådet anledning til at ændre besvarelsenerne af de tidligere stillede spørgsmål.

...«

Endelig har Retslægerådet den 24. oktober 2002 under en udsættelse af domsforhandlingen besvaret spørgsmålene 10 og A, B og C således:

»...«

Spørgsmål 10:

Retslægerådet bedes efter en gennemgang af sagens ekstrakt, sagsøgers og sagsøgtens materialesamling, sagsøgers hjælpebilag i f.m. sagsøgers forelæggelse og dokumentation samt journalark af den 29. September 1993 udarbejdet af overlæge Kai Erland Pedersen, Herning Centralsygehus vedr. B (cpr. - - -) oplyse, hvorvidt de beskrevne observationer i journalarket af den 29. September 1993 (Babinsky's tåfænomen m.v.) efter Retslægerådets opfattelse kan tages til indtægt for, at B tidligere end undersøgelsestidspunktet har haft en encefalitis eller en anden lignende alvorlig hjernepåvirkning.

Rådet har efter fornyet gennemgang af sagens ekstrakt, materialesamling og bilag samt journalbeskrivelse fra Herning, børnepsykiatrisk afdeling den 29.09.93 udarbejdet af overlæge Kai Erland Pedersen, vurderet følgende:

- Det er i juli 1992 beskrevet, at EEG var normal
- Det er i marts 1993 beskrevet, at MR-skanning af hjernen var normal. En lidt mindre størrelse af det venstre okcipitalhorn sammenlignet med det højre kan ikke anses for abnormt eller tydende på en cerebral skade.
- Overlæge Kai Erland Pedersen har i sin undersøgelse i september 1993 fundet en ganske let overvægt af senerereflekserne på den højre underekstremitet sammenlignet med den venstre, hvorimod senerereflekserne var egale på overekstremiteterne. Ved strykning under fodsålerne fandtes et Babinski tåfænomen, hvor storetåen bevæges op efter på højre side, hvorimod storetåen bevægedes nedefter på venstre side. Babinskis tåfænomen er normalt til stede på begge sider ved fødslen og erstattes gradvist under opvæksten af en nedadbøjning af storetåen, således som det ses hos ældre børn og voksne.
- I sagens akter er der ikke andre undersøgelser end den fra september 1993 af refleksforholdene på underekstremiteterne til belysning af, om det var et enkeltstående fund eller et fund, der kunne reproducere ved gentagne undersøgelser.

På denne baggrund må Retslægerådet konkludere, at de fundne refleksforstyrrelser i højre ben kan være forenelige med, men ikke behøver at være udtryk for en forudgående tidligere hjernepåvirk-

ning. EEG og MR-undersøgelsen taler mod, men udelukker ikke nødvendigvis en tidligere hjernepåvirkning.

Spørgsmål A:

Er undersøgelsesresultaterne i journalen fra Herning Centralsygehus den 29. september 1993 udtryk for, at den stedfundne MFR-vaccination har forårsaget autismen - eller en lidelse (hjernebetændelse eller lignende), der herefter har forårsaget autismen hos B?

De beskrevne refleksforstyrrelser kan ikke tages som udtryk for, at den forudgående MFR-vaccination har forårsaget patientens autisme eller en mulig sammenhængende hjernepåvirkning.

Spørgsmål B:

Giver undersøgelsesresultaterne i journalen fra Herning Centralsygehus den 29. september 1993 Retslægerådet anledning til ændre nogle af svarene på de tidligere stillede spørgsmål 1-9?

De beskrevne undersøgelsesresultater giver ingen anledning til ændring af tidligere fremsendt svar på spørgsmål 1-9.

Spørgsmål C:

Giver sagen herefter Retslægerådet anledning til yderligere bemærkninger?

Nej.

...«

Der er under domsforhandlingen foruden de videnskabelige artikler, som er omtalt i sagsøgtens afgørelse og i besvarelsenerne fra Retslægerådet, henvist til en række andre videnskabelige artikler m.v., der bl.a. beskæftiger sig med en mulig sammenhæng mellem hjernebetændelse og autisme og mellem MFR-vaccination og autisme. Det drejer sig bl.a. om en artikel fra Schizophrenia Bulletin 1981 af Marian LK Demyer m.fl., hvori omtales en undersøgelse fra 1979, hvor der i 149 tilfælde af autisme hos børn blandt en del andre årsager også er beskrevet hjernebetændelse som årsag til autismen. Det drejer sig endvidere om en artikel fra The New England Journal of Medicine fra november 2002 af Kreesten Meldgaard Madsen m.fl. vedrørende resultaterne af en undersøgelse af 537.303 børn, hvori det konkluderes, at der er stærk formodning mod, at MFR-vaccination er årsag til autisme.

Der er den 11. marts 2002 afgivet forklaring af sagsøgerens mor og af overlæge Kai Erland Pedersen.

M har forklaret, at hun er mor til sagsøgeren og C, der er enæggede tvillinger. Hun har sammen med

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ægtefællen yderligere to drenge, der er ældre. Drengene er MFR-vaccineret, og de har ikke haft andre bivirkninger end lidt feber. Tvillingerne var små ved fødslen, hvorfor hun var lidt bekymret for deres vækst, men børnene udviklede sig indtil vaccinationerne den 3. april 1992 normalt. B var den dominerende af tvillingerne. Inden vaccinationen kravlede pigerne, og der var god kontakt. Pigerne fulgte det almindelige undersøgelses- og vaccinationsprogram, hvorfor hun heller ikke var i tvivl om, at pigerne skulle MFR-vaccineres. B var ved vaccinationen lidt småsnottet, men lægen sagde, at det ikke betød noget. Hun fik oplyst, at der efter en uge kunne komme lidt feber. Hun mener, at børnene blev vaccineret en fredag og ca. 10 dage senere - en søndag - fik pigerne omkring 39 i feber. Om tirsdagen var morgentemperaturen nede på 37-38, men om aftenen havde B 39,3. C havde også høj feber. En time efter at B var kommet i seng, skreg hun meget højt og havde en temperatur på 40,3. Hun kontaktede derfor vagtlægen, og hun fortalte om vaccinationen. Lægen sagde, at der ikke kunne være nogen sammenhæng, men han ville gerne se på pigerne. Hun kørte dem til lægevagten, hvor de blev undersøgt af en anden læge. Denne sagde efter at have undersøgt B i halsen, at hun havde en infektion i halsen, og hun fik noget penicillin. Dagen efter kontaktede hun sin egen læge, da hun var mest tryk ved ham. De talte kun sammen i telefonen, og han ordinerede en anden type penicillin, da den

første kunne give dårlig mave. I løbet af nogle dage blev begge piger feberfri og tilsyneladende raske. Efter 3-4 uger blev hun klar over, at der var noget helt galt med B, da hun ikke reagerede, når hun blev kaldt på, ligesom man ikke kunne få øjenkontakt med hende. B kunne sidde i timevis og tage et stykke legetøj op og slikke på det. Tvillingernes indbyrdes leg forsvandt, og C begyndte at blive aggressiv over for B, uden at B forsvarede sig. De fik derfor en mistanke om, at hun ikke kunne høre. Vidnets forældre havde også bemærket, at der var noget galt, da B ikke kunne støtte på benene som tidligere. Vidnet kontaktede lægen, og de blev i første omgang henvist til en ørelæge, der kun fandt en svag hørenedsættelse på det ene øre. Hørenedsættelsen kunne ikke forklare B's symptomer, hvorfor hun blev henvist til høreklubben, hvor der imidlertid var lang ventetid. Derfor fik hun lægen til i stedet at henvise B til børneafdelingen på Herning Centralsygehus. Her blev de taget alvorligt af læge Malgorzata Pulczynska, og da vidnet nævnte vaccinationen, gik lægen straks ud og ringede til Statens Seruminstitut. Det blev aftalt, at B skulle indlægges til udredning, hvilket skete. Man kunne imidlertid ikke umiddelbart finde ud af, hvad B fejlede, hvorfor der blev taget kontakt til børnepsykiatrisk afdeling, der i løbet af november 1992 stillede diagnosen infantile autisme. B, der nu er 11 år, har i dag et flot sprog, men hun er noget reserveret. Hun har lidt svært ved at lære. Pigerne går i hver sin specialklasse i Herning, hvor de skal gå til og med 9. klasse. B bliver meget let vred, men er også nem at gøre glad igen. Hun vil formentlig aldrig kunne klare sig selv, og skal derfor nok bo i bofællesskab eller lignende, når hun bliver voksen. C's form for autisme - Aspergers Syndrom - er en mildere form end B's. De koncentrerer sig så meget om B, at de nok i en længere periode overså C's problemer, som først viste sig, da hun blev lidt ældre. Når man har Aspergers syndrom, er man normalt begavet, men skal have meget trykke rammer. C vil muligvis med lidt støtte blive i stand til at klare sig selv.

Overlæge Kai Erland Pedersen har forklaret, at han har beskæftiget sig med børnepsykiatri i over 20 år. Han har været overlæge siden 1982. Encephalitis er en hjernebetændelse, som bl.a. opstår efter en infektion med en bakterie eller en virus. Hjernebetændelse opstår oftest via smitte. Den oftest forekommende årsag til hjernebetændelse er herpesvirus, men i sjældnere tilfælde har årsagen været smitte med morbillivirus - mæslinger. Symptomerne på hjernebetændelse er bl.a. høj feber, bevidsthedsforstyrrelser, kramper og lammelser. At et barn ikke kan høre eller ikke reagerer, er ikke tegn på bevidsthedsforstyrrelse, som ofte må identificeres ved at spørge f.eks. moren om barnets adfærd. Han har ikke set hjernebetændelse som følge af morbillivirus i den akutte fase, men han har undersøgt børn med følgeskader. Han ved ikke, hvor lang tid den akutte fase varer, men den vil nok være nogle uger. Ved smitte med morbillivirus vil barnet starte med at være forkølet og derefter få udslet. En eventuel hjernebetændelse vil først opstå senere. Ventriklene er væskefyldte hulrum i hjernen. Hvis noget hjernevæv er gået tabt, vil hulrummet være større. Hjernevæv kan fortabes for eksempel på grund af hjernebetændelse. Ventriklene er oftest symmetriske ved raske børn. Asymmetriske ventrikler kan være tegn på, at der har været hjernebetændelse, men er ikke nok til at stille diagnosen. Hvis man skal undersøge en patient for hjernebetændelse, vil man lave en prøve af rygmarvsvæsken for at undersøge for forhøjet protein. Hvis dette er tilfældet, kan man undersøge, hvilket antistof der er tale om, for på den baggrund at finde ud af, hvilken infektion patienten har haft. Han ved ikke, hvor lang tid efter den akutte fase man kan finde eventuelle proteiner. I en udenlandsk artikel er der nærmere redegjort for en undersøgelse, hvor man har undersøgt 18 personer med autisme. Heraf blev i 17 tilfælde fundet asymmetriske ventrikler. Han har selv undersøgt

en grønlandsk dreng, der udviklede autisme efter hjernebetændelse. I det tilfælde var man enige om, at drengen havde udviklet sig normalt, indtil han pådrog sig en infektion. Vidnet har undersøgt yderligere to patienter, hvor der var mistanke om, at en

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hjernebetændelse var årsag til autisme. Han er også bekendt med udenlandsk litteratur, der beskriver tilfælde af autisme efter hjernebetændelse. Professor Eric Hollander har i en meget respekteret artikel fra 1999 i CME Reviews beskrevet, at der skal to faktorer til autisme, nemlig en genetisk disposition og en neurologisk forstyrrelse. Selv om man er genetisk disponeret for en sygdom, er man ikke syg, da man kan udelukke den udløsende faktor. Man kan således være genetisk disponeret for autisme uden at blive syg. Hvis man ikke er genetisk disponeret, kan man ikke udvikle autisme. Den udløsende faktor kan for eksempel opstå under graviditeten, være selve fødslen eller en hjernebetændelse. Hvis man ikke er autist fra fødslen, skal der en neurologisk forstyrrelse til for at udløse autisme. De fleste autister er autister fra fødslen, men det kan være vanskeligt at diagnosticere så tidligt. Autismen er mangelfuld evne til at dele en oplevelse med andre. Dette viser sig blandt andet ved manglende blikkontakt. B har klassisk autisme. Vidnet har diagnosticeret C, der har en meget mildere form for autisme, kaldet Aspergers Syndrom. En person med Aspergers Syndrom udvikler sprog og er ikke mentalt retarderet. Da tvillingerne er enæggede, er de genetisk identiske. Hvis den udefrakommende påvirkning er ens, vil udviklingen derfor også være ens. Han så B første gang den 17. juli 1992, hvor læge Malgorzata Pulczynska tilkaldte ham til børneafdelingen, hvor B var blevet indlagt. Han fik straks mistanke om, at der var tale om autisme. Hans nærmere undersøgelser bekræftede mistanken. Han havde ikke på dette tidspunkt nogen mistanke om årsagen til autismen, men bad Malgorzata Pulczynska foretage de fornødne fysiske undersøgelser. En rygmarvsprøve er ikke mere belastende for barnet end en blodprøve. En rygmarvsprøve foretages for at udelukke en alvorlig lidelse i centralnervesystemet, herunder navnlig meningitis og leukæmi. Han har ikke været med til at anmelde B's sygdom som en vaccinationsskade og fik først senere at vide, at der var mistanke herom. Det tidsmæssige sammenfald mellem vaccinationen og sygdommens debut giver anledning til overvejelser, men han kan som psykiater ikke udtale sig om årsagssammenhængen. På baggrund af den tidsmæssige sammenhæng og erfaringerne med tripelvaccinen vil han dog bestemt ikke udelukke, at der er en årsagssammenhæng. Han vurderer, at B var sund og rask før vaccinationen. Han er enig i Retslægerådets besvarelse af spørgsmål 3, men hjernebetændelse er som sagt ikke den hyppigste årsag til autisme. Han er ikke enig i Retslægerådets besvarelse af spørgsmål 5 og 8, da de kliniske fund burde give anledning til overvejelse. Den 29. september 1993 konstaterede han ved en undersøgelse af B, at hun havde refleksforandringer i det ene ben, men han er ikke blevet anmodet om at udlevere resultatet af denne undersøgelse til brug for sagen. Retslægerådet burde have indhentet yderligere oplysninger, ligesom man kunne have foretaget yderligere undersøgelser. Han er heller ikke enig i Retslægerådets besvarelse af spørgsmål 6, da forandringerne af ventriklene hos autister er meget små. Han mener, at Retslægerådets besvarelse af spørgsmål 7 er direkte forkert, idet det er dokumenteret, at hjernebetændelse kan medføre tidligt infantilt autistisk syndrom. Skal besvarelsen imidlertid forstås således, at hjernebetændelse ikke altid medfører tidligt infantilt autistisk syndrom, er han enig i Retslægerådets besvarelse. Retslægerådets besvarelse af spørgsmål 9 er han enig i, men erfaringen viser ofte, at de tilfældige sammentræf alligevel har en sammenhæng.

Sagsøgeren har til støtte for sin principale påstand gjort gældende, at det med rimelig sandsynlighed er godtgjort, at hendes lidelse - tidligt infantilt autistisk syndrom - er en følge af vaccinationen den 3. april 1992. Udtrykket »rimelig sandsynlighed« i vaccinationserstatningslovens § 1 må sprogligt opfattes som et klart mere lempeligt krav end »overvejende sandsynlighed« og må antages at svare til, at en sammenhæng ikke kan udelukkes, og at der ikke kan stilles krav om overvægt af sandsynlighed. Landsretten kan i den forbindelse foretage en tilbundsående prøvelse af sagsøgtes afgørelse vedrørende årsagssammenhæng mellem vaccinationen og sagsøgerens autisme.

Det må efter bevisførelsen lægges til grund, at sagsøgeren var sund og rask og alderssvarende inden vaccinationen, jf. Retslægerådets besvarelse af spørgsmål 1. Det er endvidere med overvejende sandsynlighed godtgjort, at sagsøgeren udviklede en form for hjernebetændelse (encephalitis) 10-12 dage efter vaccinationen, idet de fremførte indikationer alle entydigt peger i den retning. Sagsøgeren har til støtte herfor blandt andet henvist til, at sagsøgeren ca. 10-12 dage efter vaccinationen havde symptomer, der ligner halsbetændelse, herunder høj feber (41 grader den 14. april 1992), hvilket er beskrevet som en indikation for encephalitis. Endvidere har sagsøgeren henvist til moderens forklaring om sagsøgerens tilstand, herunder at forældrene efterfølgende konstaterede bevidsthedsforstyrrelser, krampe og motoriske problemer hos hende, en artikel i et lægevidenskabeligt tidsskrift fra 1973, vagtlægens journaltilførsel, påvisningen af let asymmetri af de laterale sideventrikler i forbindelse med en undersøgelse på Skejby Sygehus i 1993, 1. reservelæge Malgorzata Pulczynskas mistanke om hjernebetændelse, jf. skrivelse af 4. januar 1993, og refleksforstyrrelserne. Retslægerådet har da også udtalt, at observationerne ikke udelukker, at sagsøgeren kan have haft hjernebetændelse. Det må derfor efter sagsøgerens opfattelse lægges til grund, at

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MFR-vaccine (især mæslingevaccinen) kan medføre hjernebetændelse (encephalitis).

Endvidere har sagsøgeren gjort gældende, at det med mere end overvejende sandsynlighed kan lægges til grund, at hjernebetændelse kan udløse autisme, og har i den forbindelse henvist til flere videnskabelige artikler m.v., hvorefter der ikke kan afvises en forbindelse mellem hjernebetændelse og autisme. Denne antagelse om en sammenhæng mellem vaccinationen, hjernebetændelsen og autismen afvises da heller ikke umiddelbart af flere af de i sagen involverede læger.

Sagsøgerens lidelse (tidligt infantilt autistisk syndrom) efter vaccinationen er en livsvarig skade. Der er intet, der tyder på, at sagsøgeren skulle have været arveligt disponeret for autisme. Den omstændighed, at tvillingsøsteren har udviklet en mildere form for autisme, er ikke bevis for, at sagsøgeren har været arveligt disponeret.

Det kan endvidere konstateres, at lægevidenskaben herudover generelt heller ikke kategorisk afviser en mulig sammenhæng mellem MFR-vaccinen og autisme, men det konstateres, at der p.t. intet 100% sikkert bevis er for antagelsen. Moderens oplysninger om, hvordan B ændrede personlighed efter vaccinationen og den tidsmæssige sammenhæng mellem vaccinationen og diagnosen infantil autisme sandsynliggør imidlertid årsagssammenhæng mellem vaccinationen og autismen. Sagsøgeren har endvidere anført, at det er uden betydning, om sagsøgeren eventuelt har været genetisk disponeret for at udvikle autisme, idet det afgørende er, om vaccinationen udløste autismen. Sagsøgeren har i den forbindelse henvist til overlæge Kai Erland Pedersens forklaring. Det kan endvidere konstateres, at der er et tidsmæssigt sammenfald mellem vaccinationen og skaden, og dette fører - sammenholdt med de

øvrige omstændigheder - til, at sagsøgeren har ført det fornødne bevis for årsagssammenhæng mellem vaccinen og autismen.

Til støtte for den subsidiære påstand har sagsøgeren gjort gældende, at der i sagen specielt og forskningen på området generelt, er fremkommet så mange nye oplysninger, at dette bør medføre, at sagsøgerens sag undergives en ny grundig behandling i Arbejds-skadestyrelsen eller i Den Sociale Ankestyrelse.

Sagsøgte har til støtte for sin påstand gjort gældende, at sagsøgtes afgørelse truffet i møde den 18. december 1996 er korrekt, og at der ikke er grundlag for at tilsidesætte sagsøgtes sagkyndige bedømmelse af, at den af sagsøgeren anmeldte lidelse i form af autisme ikke med rimelig sandsynlighed må antages at være forårsaget af MFR-vaccinationen den 3. april 1992, jf. vaccinationserstatningslovens § 1, stk. 1.

Sagsøgte har gennem behandlingen af disse sager en særlig erfaring i at bedømme, om lovens betingelser er opfyldt. Sagsøgte har under medvirken af rådgivende speciallægekonsulenter truffet sin afgørelse efter et skøn over samtlige foreliggende konkrete omstændigheder, herunder den af sagsøgte indhentede udtalelse fra Retslægerådet. Der skal derfor foreligge et sikkert grundlag for at tilsidesætte sagsøgtes afgørelse.

Bevisbyrden for, at der er rimelig sandsynlighed for årsagssammenhæng, påhviler sagsøgeren. Det gøres i den forbindelse gældende, at kravet om rimelig sandsynlighed indebærer, at der skal være en overvægt af sandsynlighed for årsagssammenhæng, og at der i kravet om rimelig sandsynlighed ikke på noget sted i bevisrækken kan indfortolkes et formodningsprincip, der indebærer, at sagsøgte skal modbevise årsagssammenhæng.

Det gøres endvidere gældende, at MFR-vaccine ikke i sig selv kan forårsage autisme. MFR-vaccinationen den 3. april 1992 har hverken forårsaget autisme hos sagsøgeren eller har forårsaget sådanne lidelser hos sagsøgeren, som kan medføre autisme. Årsagen til, at sagsøgeren udviklede infantil autisme, skal, henset til at sagsøgerens tvillingsøster har fået stillet diagnosen Aspergers Syndrom, snarere søges i genetiske faktorer end i de stedfundne vaccinationer. Det bestrides derfor, at sagsøgeren var sund og rask før vaccinationen.

Det gøres herved gældende, at de lægelige undersøgelser ikke med rimelig sandsynlighed har godtgjort, at sagsøgeren udviklede hjernebetændelse i tilslutning til vaccinationen. Forløbet efter vaccinationen er ikke udtryk for tilstedeværelsen af hjernebetændelse, men må betragtes som en hel naturlig vaccinationsreaktion. Der er ikke i øvrigt påvist forhold, der godtgør en hjernebetændelse, endsige antyder dette. Endelig opstod temperaturforhøjelsen først omkring 10 døgn efter vaccinationen.

Sagsøgte har i den forbindelse bestridt, at hjernebetændelse kan medføre autisme, men har ikke bestridt, at mæslinger og mæslingevaccine kan medføre hjernebetændelse.

Det bestrides endvidere, at det tilfældige tidsmæssige sammenfald mellem vaccinationen og lidelsens debut er tilstrækkeligt til at antage rimelig sandsynlighed for årsagssammenhæng eller vil medføre en formodning for årsagssammenhæng med den konsekvens, at sagsøgte skal modbevise årsagssammenhæng.

Det gøres gældende, at det forhold, at MFR-vaccinationen er et gratis tilbud, som enhver kan fravælge efter vurdering af risici, ikke medfører lempelser i kravet til årsagssammenhæng, endsige skærper pligten til at betale erstatning.

Der skal ved vurderingen af, om der foreligger et sikkert grundlag for at tilsidesætte sagsøgtes afgørelse, alene skal tages hensyn til den lægefaglige viden, der forelå på tidspunktet for sagsøgtes afgørelse. Efterfølgende undersøgelsesresultater, herunder revurderinger

af allerede foretagne undersøgelser, som eventuelt måtte kunne begrunde antagelser om årsagssammenhæng, kan ikke påvirke gyldigheden af sagsøgtets afgørelse, men vil i givet fald kunne begrunde en begæring til Arbejdsskadestyrelsen om administrativ genoptagelse af sagen. Den nyeste forskning og de nyeste artikler i lægevidenskabelige tidsskrifter har imidlertid ikke påvist en sammenhæng mellem MFR-vaccinen og autisme - tværtimod. Bevisførelsen under retssagen kan heller ikke føre til ændring af sagsøgtets afgørelse.

Landsrettens begrundelse og resultat:

Landsretten har ved sagens afgørelse lagt til grund, at udtrykket »rimelig sandsynlighed« i § 1 i lov om erstatning for vaccinations-skader skal forstås således, at det indeholder en lempelse af de sædvanlige krav til beviset for årsagssammenhæng i en erstatnings-sag, men at der skal være en overvejende sandsynlighed (mere end 50 %) for, at skaden er forvoldt af vaccinationen.

Det må efter Retslægerådets svar på spørgsmål 1 i den første erklæring af 6. februar 1996 antages, at sagsøgeren efter al sandsynlighed har været helt normalt udviklet frem til vaccinationstidspunktet.

Retslægerådet har i den første erklæring i svaret på spørgsmål 3 udtalt, at de foreliggende oplysninger ikke med rimelig sandsynlighed kan godtgøre, at sagsøgeren udviklede hjernebetændelse som følge af MFR-vaccinationen. I den sidste erklæring af 24. oktober 2002 har Retslægerådet udtalt, at de fundne refleksforstyrrelser i højre ben kan være forenelige med, men ikke behøver at være udtryk for en forudgående tidligere hjernepåvirkning.

Disse vurderinger er ikke uforenelige med overlæge, speciallæge i børnepsykiatri Ingelise Sillesens vurdering i dennes erklæring af 11. februar 1994, hvorefter Ingelise Sillesen, som sygdomsbilledet har udviklet sig, synes, at der er begrundet mistanke om, at sagsøgeren kan have haft hjernebetændelse, men om hjernebetændelsen er forårsaget af vaccinationen, kan overlægen ikke udtale sig om, ud over at der er en »vis sandsynlighed« herfor på grund af det tidsmæssige sammenfald.

Retslægerådet har i den første erklæring udtalt, at der efter hjernebetændelse vil kunne forekomme varige psykiske skader, men kun sjældent i form af den foreliggende tilstand af infantil autisme. Retslægerådet har i den anden erklæring af 2. juli 1998 ved besvarelsen af spørgsmål 7 anført, at der ikke er sikre holdepunkter for, at hjernebetændelse medfører tidligt infantilt autistisk syndrom.

Efter en samlet vurdering af de tilvejebragte lægelige oplysninger, herunder især Retslægerådets besvarelser af de stillede spørgsmål, og det i øvrigt foreliggende, herunder oplysningerne om sammenfaldet mellem vaccinationen og sygdomsudviklingen og de afgivne forklaringer, finder landsretten ikke, at der er rimelig sandsynlighed for, at sagsøgerens autisme er forårsaget af vaccinationen og en deraf følgende hjernebetændelse. Heller ikke den seneste artikel i et lægevidenskabeligt tidsskrift om MFR-vaccination og autisme peger på, at der er en rimelig sandsynlighed for, at MFR-vaccination kan medføre autisme.

Idet der heller ikke er grundlag for at tage sagsøgerens subsidiaire påstand til følge, tager landsretten sagsøgtets påstand om frifindelse til følge.

- - -

Ingen af parterne skal betale sagsomkostninger til den anden part eller til statskassen.

Højesteret

Højesterets dom.

I tidligere instans er afsagt dom af Vestre Landsrets 13. afdeling den 12. marts 2003.

I pådømmelsen har deltaget fem dommere: Poul Sørensen, Per Sørensen, Poul Søgaard, Jytte Scharling og Jon Stokholm.

Påstande

Appellanten, B, har principalt påstået indstævnte, Ankestyrelsen, dømt til at anerkende, at hendes lidelse (tidligt infantilt autistisk syndrom) med rimelig sandsynlighed må antages at være en følge af den vaccination, hun modtog den 3. april 1992 mod bl.a. mæslinger, fåresyge og røde hunde (MFR-vaccination), og dermed omfattet af vaccinationserstatningsloven. Subsidiært har hun påstået sagen hjemvist til fornyet behandling i Ankestyrelsen.

Ankestyrelsen har påstået stadfæstelse.

Appellanten har for Højesteret henvist til yderligere lægevidenskabelig litteratur.

Højesterets begrundelse og resultat

Indledningsvis bemærkes, at første led i appellants principale påstand må anses som et anbringende til støtte for andet led i påstanden og derfor ikke kan medtages som del af påstanden.

Af de grunde, der er anført af landsretten, og da det, der er fremkommet for Højesteret, ikke kan føre til et andet resultat, stadfæster Højesteret dommen.

Thi kendes for ret:

Landsrettens dom stadfæstes.

I sagsomkostninger for Højesteret skal statskassen inden 14 dage efter denne højesteretsdoms afsigelse betale 50.000 kr. til Ankestyrelsen.